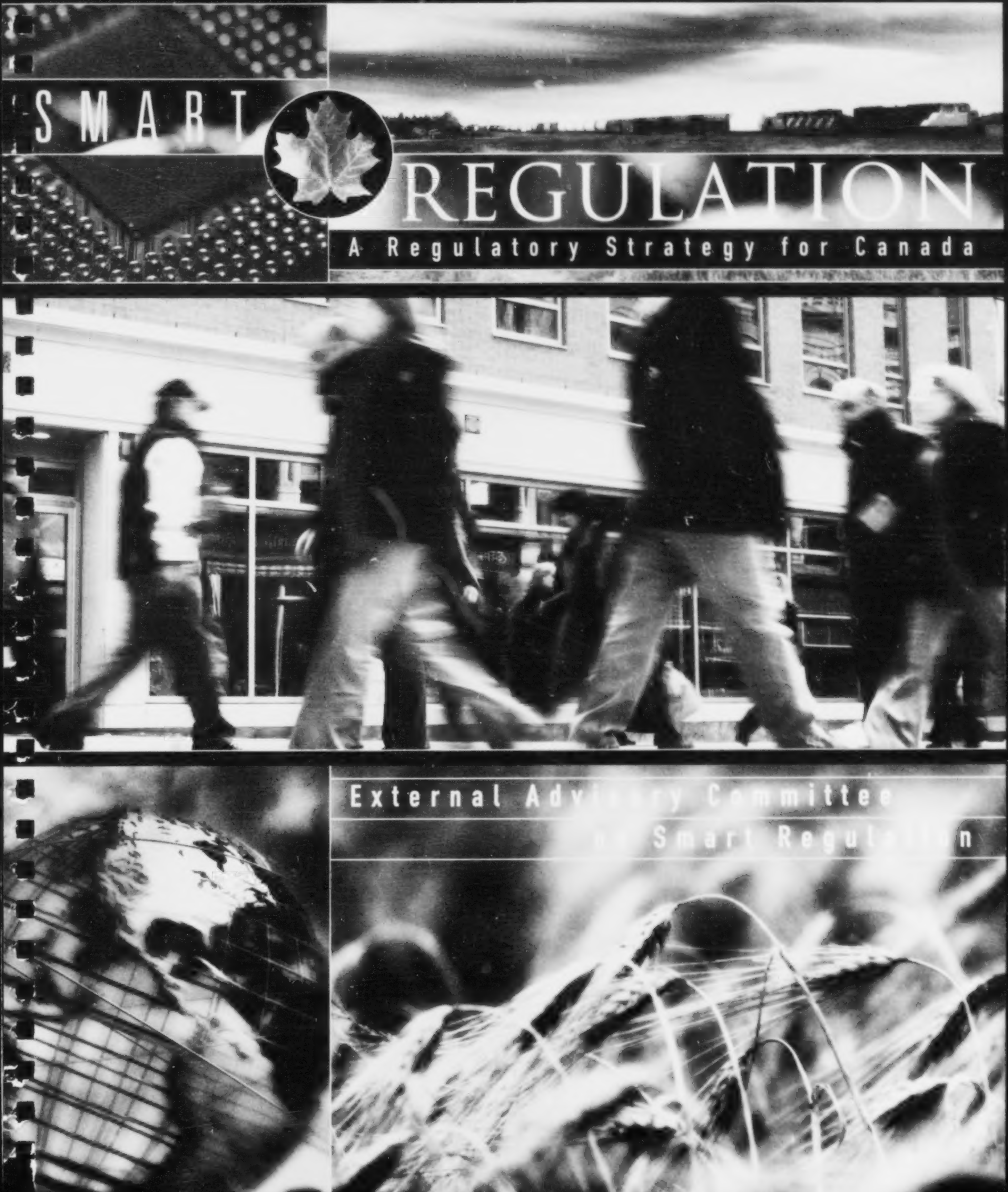
SMART REGULATION

A Regulatory Strategy for Canada



External Advisory Committee on Smart Regulation

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SMART REGULATION

A Regulatory Strategy for Canada

Report to the Government of Canada

External Advisory Committee on Smart Regulation
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MESSAGE FROM THE CHAIR

I am very proud to present the final report of the External Advisory Committee on Smart Regulation. I accepted the invitation to chair this Committee a little over a year ago because I was convinced that there is a connection between regulation and the high quality of life enjoyed by Canadians and yet, at the same time, I observed an increasingly profound disconnect between the regulatory system and 21st century reality. I was deeply concerned that without rapid and significant change, Canada's ability to innovate and provide citizens with high levels of protection would be impaired.

The Committee and I brought to the task a strong commitment and a huge desire to be agents of change. Change must be anchored within a solid value system. As a Committee, we spent considerable time defining the vision and principles underpinning the value system of Smart Regulation, an approach which remains the foundation of the report's recommendations. Our definition of success as a Committee included not only developing innovative recommendations but also facilitating profound change in the practices and culture of regulatory departments. We are pleased to report that we have already begun to witness this change and it is our hope that this report will help to accelerate and sustain it.

Over the last year, as I was talking about the work of the Committee, I was often told — although not cynically — that I was an idealist. I admit that the bar we are setting in this report is high. However, anything lower would imply that we do not trust in the ability of the government and federal public servants to take up this challenge, and we have no reason to believe that they are not up to it.

To meet this challenge, strong leadership at the senior political and public service levels will be required. Regulation is an important and powerful government intervention and must receive the attention it deserves.

Regulation is not only the business of government. Committee members are convinced that the transformation of the regulatory system will be realized only through increased cooperation among governments, industry, non-governmental organizations and interested citizens. Committee members believe that the principles of cooperation, timeliness and transparency should be embraced by all of these partners in the regulatory process. It is, therefore, our sincere hope that they, too, will be influenced by the work of the Committee.

Committee members want to thank the federal officials involved in regulation for the continuous support and openness they have shown us and our staff from the outset of this project. Our thanks also go to the different representatives from industry and non-governmental organizations, as well as the citizens who care about the regulatory system in Canada, for taking the time to share their experiences and perspectives on regulation with the Committee. We also appreciate the creativity and support of our Secretariat, whose dedication and enthusiasm have benefited the Committee's work over these past 15 months. All this support was necessary for the Committee to accomplish its mandate. I also want to express gratitude to my colleagues on the Committee who brought energy, generosity and respect to the task and made our work a learning experience.

Finally, it has been a privilege to serve my country as Chair of this Committee. The Committee hopes that its work will contribute to a permanent legacy that will improve the quality of life of all Canadians.

Gaëtan Lussier

External Advisory Committee on Smart Regulation

Chair

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PREFACE

The External Advisory Committee on Smart Regulation was established in May 2003 to provide an external perspective and expert advice on how the federal government needs to redesign its regulatory approach for Canada in the 21st century. A number of factors are increasing the rate of change in the world — global markets and the greater mobility of people and skills, rapid scientific and technological advancements, cross-boundary health and environmental risks, and the growing empowerment of citizens. It is against this backdrop that the Committee examined areas where the federal government needs to improve, expand or possibly redesign its regulatory approach.

The Committee comprises 10 members with extensive experience and diverse backgrounds. Its terms of reference were to:

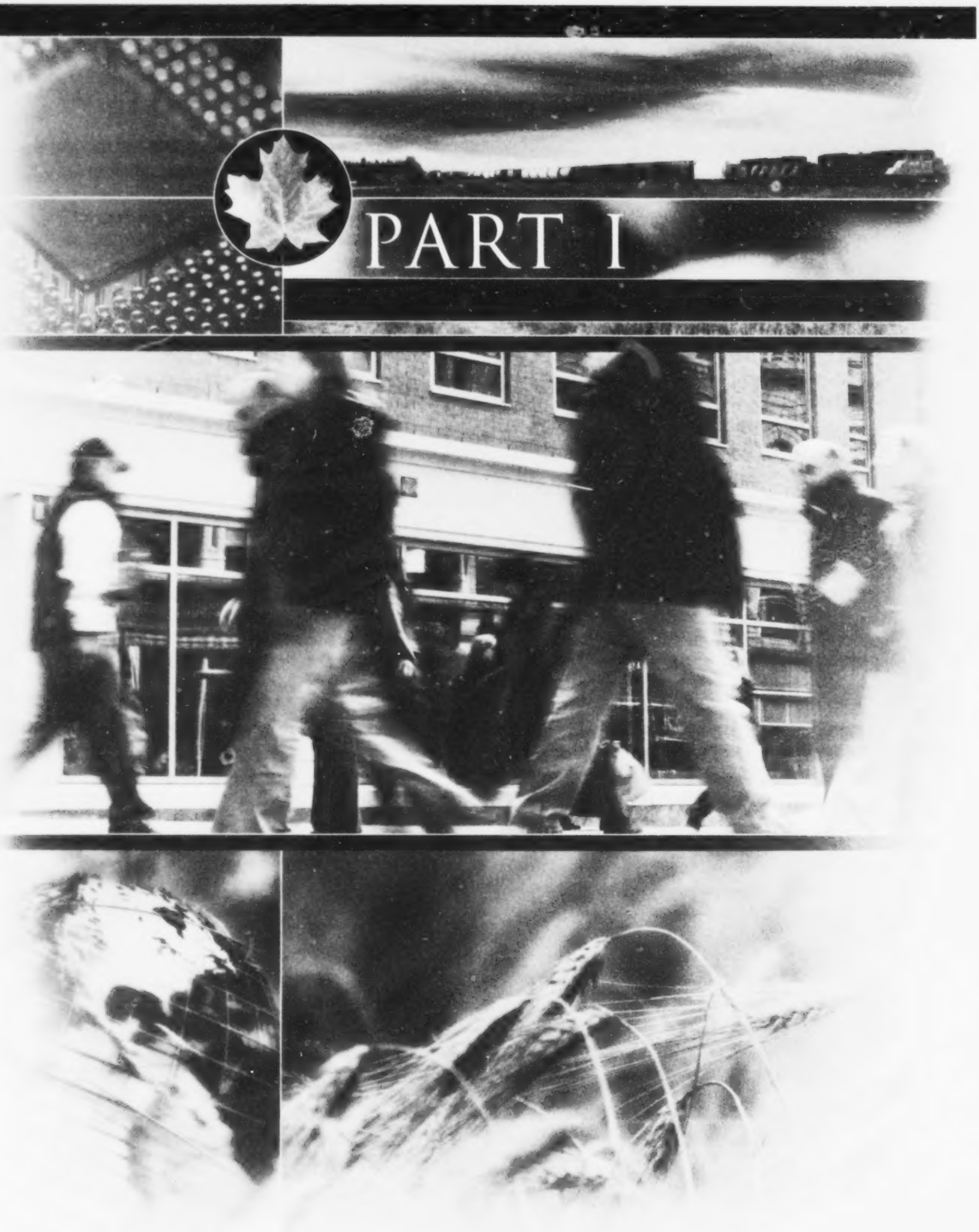
- develop a regulatory strategy designed for the 21st century, supporting Canada as a sovereign trading nation that offers a high quality of life for its citizens;
- identify sectors and areas requiring regulatory reform in order to give Canada a strategic advantage; and
- review and provide an external perspective on specific issues identified by departments and stakeholders.

The Committee was asked to fulfill its mandate within 12 to 15 months. Given this timeline and limited resources, the Committee decided to focus its work on certain areas over others. For example, it did not address key market framework legislation or areas where an existing review process was already under way, such as the various reviews of securities regulation and the study of cost recovery measures by the Treasury Board Secretariat. The Committee decided not to deal with regulation related to climate change because, at the time the Committee was created, this issue was already the subject of extensive discussions among the federal government, the provinces and territories, the private sector and other stakeholders.

The Committee did not conduct a detailed study of the regulatory burden on business, although it hopes that its recommendations will help in this regard. The Committee acknowledges the recent work of provinces and territories to reduce the burden on small and medium-sized enterprises. It also notes the recent Federal Budget commitment to establish a joint working group on paperwork burden reduction, which will be co-chaired by Industry Canada and an association representing small businesses.

The Committee believes that the issues identified in this report and many of its recommendations are relevant for most sectors of the economy. It recognizes that much of its analysis and therefore many of the examples in this document are related to what the Organisation for Economic Co-operation and Development defines as "social regulation," in other words, health, safety, environmental and other areas of protective regulation. These are the types of regulations that are expanding the most rapidly and have generated the most criticism and the greatest expectations from citizens. In addition, given the fast pace of developments in the fields of science and technology, social regulation is where many of the regulatory challenges of the future will occur. Considering the potential economic opportunities and social benefits involved, the Committee felt that it would therefore be opportune to focus on social regulation. 🍁

PART I



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OVERVIEW

The External Advisory Committee on Smart Regulation recommends major shifts in perspective and practice in this report. Canada has a sound regulatory foundation. But the Committee has found that the regulatory system is being challenged daily to be more effective, responsive, cost-efficient, transparent and accountable to Canadians.

The context in which the system operates has changed. Protecting citizens, consumers and the natural environment is a more demanding task in the 21st century. Businesses must perform more efficiently and be more innovative in a highly integrated international economy. Perhaps not surprisingly, the Committee heard from every major sector that the current regulatory system often acts as a constraint to innovation, competitiveness, investment and trade.

But Smart Regulation, as defined by the Committee, is not deregulation. Smart Regulation does not diminish protection, as some may fear. It strengthens the system of regulation so that Canadians can continue to enjoy a high quality of life in the 21st century. The Committee believes that regulation should support both social and economic achievement — providing citizens with the protection they need to feel safe, supporting the transition to sustainable development, encouraging a more dynamic economy and creating opportunities for Canadians and a model of regulatory excellence in the world.

The Committee's challenge was to identify how to improve the regulatory system in order to sustain Canada's well-being into the future. It has concluded that this objective cannot be realized without cooperation among governments, industry and citizens, which is why cooperation is at the heart of the Committee's proposed new regulatory strategy for Canada outlined in Part I of this report. Cooperation anchors its vision and principles statement and underlies many of its recommendations. The Committee believes strongly that a high-performing 21st century system requires better and closer relations between the partners in the system — governments, government departments, industry, citizens/consumers and other stakeholders — based on improving information, transparency and trust.

What is Regulation?

Regulation in its broadest sense is equated with governing. It is a principle, rule or condition that governs the behaviour of citizens or enterprises. In this way, regulation is used by governments, in combination with other instruments such as taxation, program delivery and services, to achieve public policy objectives. Regulation is a key way by which governments work to protect the health, safety and socio-economic well-being of Canadians as well as Canada's natural environment. It contributes to ensuring a fair and efficient marketplace for industry and consumers. It also plays a role in establishing and maintaining market access and creating a climate conducive to trade and investment.

Regulation is part of a continuum of government action, which includes scientific and policy research, policy development, the creation of legislation and/or regulations and enforcement of the regulations. A high-performing system requires a close interrelationship between all four elements.

As demonstrated in this report, regulation encompasses a range of instruments that include formal rules, such as statutes, subordinate legislation (regulations) and ministerial orders, as well as less formal instruments, such as standards, guidelines, codes, and education and information campaigns.

The Committee believes that the federal government must use regulation more strategically in the 21st century to advance Canadian interests and priorities. The way we regulate should be clearly seen to support national policies. As illustrated in Part II of the report, this means ensuring that our regulatory system supports the best health outcomes for Canadians, encourages innovation, sustainability and investment opportunities in Canada's manufacturing and natural resources sectors, enables First Nations economic development, and helps promote important new industries like biotechnology.

What Are the Consequences of Non-Action?

Regulation is a powerful instrument of government. However, the Committee has observed that it has not received the same attention as program spending and taxation. The Committee believes that Smart Regulation should become a major priority of the government, as the regulatory system is not sustainable at the level Canadians expect without fundamental and systemic changes.

If the system is not aligned with new developments and 21st century practices, it may put Canadians' safety at risk and affect citizens' trust in government. Without change, it will limit Canadians' access, for example, to new medications, cleaner fuels and better jobs. An outdated system is an impediment to innovation and a drag on the economy because it can inhibit competitiveness, productivity, investment and the growth of key sectors. Other countries are reforming their systems, and Canada cannot afford to be left behind.

Regulation in Everyday Life

Every day, the average Canadian is affected by regulation in myriad ways. The safety and nutritional quality of food are regulated by Health Canada and enforced by the Canadian Food Inspection Agency. Personal care products, such as deodorants and toothpaste, as well as drugs and medications must meet Health Canada's stringent safety requirements before they are made accessible to Canadians. Transportation and vehicle safety are regulated by Transport Canada. Regulations enforced by Environment Canada and Fisheries and Oceans Canada help protect our country's wildlife and natural habitats.

Regulations are important for an effective marketplace. The operation of businesses is regulated in terms of how they compete, the quality and safety of their products, how they manage their waste, and how they import source materials and export products interprovincially and internationally. Banks and financial institutions are regulated, as is the movement of people, goods and capital across national borders.

What Is Driving the Need for Change?

The Committee concluded that certain 21st century realities make regulatory reform essential. It found that there is general agreement within the government that the system must be changed to take these realities into account. But this recognition has not yet been translated into daily practice.

- First, the speed of modern society has resulted in an explosion of new technologies, the rapid flow of commerce and instant access to information. Businesses are continually innovating to meet changing consumer needs, cut production costs and increase their market shares. In a knowledge-based economy, regulatory regimes have to adapt quickly to sustain effective protection and keep pace with innovation and entrepreneurship.
- Second, policy issues are increasingly complex. Boundaries between once distinct areas and disciplines have become blurred (e.g. bioproducts). In addition, major new policy directions have emerged, such as sustainable development, which will have profound implications for regulators. In this changing policy context, departments and governments must increasingly work together in defining regulatory strategies.
- Third, public expectations of government have risen, and at times they conflict, as citizens ask for more freedom of choice in some areas, increased regulation in others, and greater accountability and transparency.

What Needs to be Improved?

The Committee's analysis and recommendations for improvements are set out in detail in the chapters that follow. Several key messages emerged from its deliberations and its discussions with stakeholders and government officials:

- **The importance of getting our national house in order.** The harshest criticism of current regulatory practice is the lack of cooperation and coordination between federal government departments and among federal, provincial and territorial governments. From the average consumer to the largest multinational enterprise, the Committee heard that governments need to stop fighting over jurisdiction and find ways to work together on behalf of citizens and industry.
- **The need for a more strategic international regulatory approach.** International cooperation is increasingly necessary to provide high levels of consumer, social and environmental protection. It is no longer possible to protect Canadians' health and safety and provide access to innovative products — and do it all ourselves. From a business perspective, Canada must be more strategic in its regulatory relations with trading partners. A key irritant for industry is the proliferation of minor differences between Canadian and American regulations, given an increasingly integrated North American market. Minimizing these differences would remove wasteful duplication and reduce costs for consumers, industry and government.
- **The value of other perspectives.** The Committee's deliberations were enriched and informed by the involvement of consumer, industry, Aboriginal and environmental voices. While governments have a central responsibility to maintain the regulatory system, they need the input and insights of businesses, non-governmental organizations (NGOs) and other stakeholders to ensure that the system is relevant and effective.
- **The necessity for more cost-effective, timely processes.** The Committee heard repeatedly that the government takes too long to design regulations and complete approvals. Slowness is sometimes equated with higher protection. In a fast-paced environment, however, a sluggish process can have grave implications for human and animal health. It can be the determining factor in a small Canadian business remaining viable or international investment leaving Canada in favour of a more streamlined regulatory environment elsewhere.
- **More focus on results.** Increasingly, many regulatees have the knowledge and capacity to meet regulatory goals without the need for detailed prescriptions about how they should do it. With the right monitoring and assessment strategies in place, Canada can and should be more bold in its use of performance-based regulations and other alternative instruments.
- **Better performance and accountability measurement.** The government's stakeholders want much more emphasis placed on performance and accountability in the future. The Committee found that there is no systematic review of federal regulations to determine if they are still doing the job intended, including whether they are based on the latest scientific developments, as well as their effect on citizens and businesses. The regulatory process should encourage continuous improvement. Regulators must be clear and transparent with Canadians about the results they want to achieve and how they will measure them. There must also be recourse — an independent third party — for when normal processes fail.
- **The need for cultural change.** The recommendations in this report, and the expectations of stakeholders, cannot be addressed by tinkering with the process. A major change in approach is needed, supported by training for government regulators and the commitment and drive of senior bureaucrats and parliamentarians.

Regulating in the Public Interest

Broadly speaking, regulation is meant to serve the public interest. The Committee found that there is no shared definition of the public interest among government departments. Therefore, some of its work was dedicated to developing a better overall understanding of the Canadian public interest in the 21st century[1] as well as ways to assess the public interest in specific circumstances (see Annex II, A Public Interest Accountability Framework).

Recent studies have found that Canadians' views on regulatory reform have evolved considerably since the late 1980s. Canadians are more pragmatic than ideological. Citizens' demands for protection have increased over time, particularly with respect to health, safety and the environment; however, their views go well beyond the notion that more regulation is better.

Canadians now see social, environmental and economic goals as intertwined. They believe that there is an excessive compliance burden on business. They also accept that markets, trade and competition serve both public and private interests. This represents an important change. Canadians believe that the government is ultimately responsible for the health and safety of Canadians and protection of the environment, but they are prepared to be flexible in how these objectives are attained, as long as both industry and government are accountable and achieve results. Their trust in the system will depend on the quality of the process, which they expect to be fair, open, transparent and accountable.

Canadians have little tolerance for federal-provincial conflicts and they expect departments within the same government to coordinate their actions. From an international perspective, they are generally in favour of greater cooperation, in particular through multilateral international bodies, and they will also support bilateral cooperation, including Canada-U.S. regulatory cooperation, if it means strengthened regulatory standards or if it represents a more cost-efficient way to achieve the desired results.

What is Smart Regulation?

After considering current regulatory practice in Canada and other OECD countries, and the comments of stakeholders and other governments, the Committee has concluded that there are three key characteristics of Smart Regulation:

Smart Regulation is both protecting and enabling. It involves using the regulatory system to generate social and environmental benefits while enhancing the conditions for a competitive and innovative economy that will attract investment and skilled workers and sustain a high quality of life for Canadians. It is about making regulation as effective as possible — and making sure it is never more complicated or costly than it has to be.

Smart Regulation is more responsive regulation. An effective regulatory system must be self-renewing and keep up with developments in science, technology and global markets. Smart Regulation is acting quickly and deliberately to contain or prevent risks and enable innovation and opportunity so that Canadians receive the benefits of new knowledge. This also means giving regulatees more flexibility in terms of how results are achieved, as long as high standards are upheld and the appropriate accountability measures are in place.

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[1] *Assessing the Public Interest in the 21st Century: A Framework*, by Leslie A. Pal and Judith Maxwell, and *A Public Opinion Perspective on Regulation*, by Matthew Mendelsohn.

Smart Regulation is governing cooperatively for the public interest. In a modern regulatory system, regulation is a shared responsibility in which governments, citizens and industry all have an active role to play in making the system more effective. Smart Regulation is taking into account the views of citizens and, at the same time, being attentive to, and balancing, the needs of firms and the challenges they face in an international economy. It is realizing that the regulatory system is part of a complex global system which requires governments and government departments and agencies to work better together towards common goals.

What Are the Benefits and Opportunities for Canada?

In summary, Smart Regulation offers Canada the opportunity to:

- support and enable Canadian social, environmental and economic priorities;
- achieve high standards of protection for citizens;
- support the transition to sustainable development;
- enhance business confidence and public trust in Canada's regulatory system;
- position Canada internationally as a place to do business;
- help Canadians take advantage of new knowledge; and
- make better use of government resources.

Regulatory Renewal Around the World

Many countries around the world have embarked on regulatory renewal. The country that can best use its regulatory system to generate greater environmental and social benefits while enhancing the conditions for a competitive and innovative economy will have a comparative advantage in attracting investment and skilled workers.

While many reform efforts originally focused on the enhancement of productivity, competitiveness and other economic issues, their scope has recently been broadened to include sustainability and environmental impacts. Sustainable development analyses, for example, are undertaken in Australia, Finland, the United Kingdom and the European Union. International regulatory practice has led to an increased emphasis on the rigour of impact analyses, leading to such innovations as peer review of relevant science (U.S.) and emphasis on small business and sustainable development (Australia, EU). A recent U.S. proposal suggests special attention be given to the quality of regulations whose impact exceeds $1 billion per year.

Other areas of regulatory reform that have received increased attention include consultations (Finland, EU, Australia), improvements in accountability (U.S., U.K., Australia), regulatory oversight through such mechanisms as ombudsman processes and independent advice (U.S., U.K., Australia, EU) and the periodic review of the existing stock of regulations (Australia). In the United States, for example, the Office of Information and Regulatory Affairs publishes on its Web site the list of regulations under review, as well as monthly summaries of agency actions and information about meetings with stakeholders. The U.S. General Accounting Office also plays a role in performance management, risk management, accountability and planning.

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VISION AND PRINCIPLES

The Committee proposes the following vision and principles to guide a Smart Regulation strategy for Canada.

Vision

Governments, citizens and businesses will work together to build a national regulatory system that maximizes the benefits of regulation for all Canadians, enables them to take advantage of new knowledge and supports Canada's participation in an international economy. Within this vision are three components:

TRUST – The regulatory system must instil trust, confidence and credibility at home and abroad in Canadian products and services, markets and government institutions.

INNOVATION – The regulatory system must enhance market performance and support innovation, competitiveness, entrepreneurship and investment in the Canadian economy.

PROTECTION – The regulatory system must demonstrate to citizens that the public interest, which includes such issues as human health and safety and environmental protection, will be safeguarded within dynamic global markets.

Principles

This vision can be achieved by having our regulatory system, from the design stage to compliance and enforcement, adhere to the following principles:

1. **EFFECTIVENESS** – Regulation must achieve its intended policy objectives and must advance national priorities. It should be based primarily on standards and performance targets, rather than on how those targets are achieved, in order to provide flexibility while serving the public interest. Regulation should be supported by evidence and should reflect the latest knowledge. Regulatory measures must be regularly and systematically reviewed and, where necessary, eliminated or modified; and new measures must be created to take into account changing consumer preferences and expectations, scientific and technological advances and changing business environments.

2. **COST-EFFICIENCY** – Regulatory analytical requirements, measures and enforcement should be commensurate with the risks and problems involved. The appropriate instrument mix should be designed and implemented in the least costly manner possible to achieve the desired policy objectives. Single windows between departments and between jurisdictions should be offered. Regulators must understand the cumulative impact of regulation and seek to avoid overlap, duplication, inconsistency and unintended consequences.

3. **TIMELINESS** – Regulatory decisions and government services must be provided in a manner that reflects the pace at which new knowledge develops, consumer needs evolve and business now operates. Timeframes and standards for decision making should be developed and enforced.

4. **TRANSPARENCY** – The accessibility and transparency of the regulatory system must be maximized to promote learning and information sharing and to build public trust at home and abroad in the quality of Canadian regulation and the integrity of the process. Policy objectives should be clearly defined. Regulators must explain their priorities and decisions, show why and how these decisions are in the public interest, and be subject to public scrutiny. Information on regulatory programs and compliance requirements should be readily available in print and electronic formats. The regulatory system should be more predictable to provide certainty to those being regulated. Citizens and business should participate through active consultation and engagement.

5. **ACCOUNTABILITY AND PERFORMANCE** – Regulators must account for their performance. They need to announce their intended results and demonstrate their progress in achieving them. Performance should be monitored, measured and reported on publicly. Results should be used to modify regulatory programs and should be systematically reported to the public. Regulatory systems must be fair and consistent. Complaints and appeals procedures should also be established, well publicized, accessible, fair and effective. ◆

3

A REGULATORY STRATEGY FOR THE 21ST CENTURY

Introduction

As the first part of its mandate, the Committee was asked to provide its advice on a new regulatory strategy for Canada. It was asked to consider how regulation can better contribute to the achievement of Canada's social, environmental and economic objectives in the context of the 21st century — the rapid increase in scientific and technological advancements, trans-boundary health and environmental risks, greater integration of markets and companies, and citizens' growing expectations of government. The Committee recognizes that this rapidly evolving policy environment challenges the regulatory system on every front and, at the same time, calls for higher and higher standards of performance.

The Regulators' Challenge

"Regulators, under unprecedented pressure, face a range of demands, often contradictory in nature: be less intrusive — but more effective; be kinder and gentler — but don't let the bastards get away with anything; focus your efforts — but be consistent; process things quicker — and be more careful next time; deal with important issues — but do not stray outside your statutory authority; be more responsive to the regulated community — but do not get captured by industry."

The Regulatory Craft, Malcolm Sparrow (2000)

The Committee's proposed strategy is based on the vision and principles of Smart Regulation set out in the previous chapter. The strategy describes, in effect, how to put the principles into practice and realize the vision of Smart Regulation for Canada over the next three to five years. It sets out proposed directions and recommendations regarding international regulatory cooperation, federal-provincial-territorial regulatory cooperation, federal coordination, risk management, instruments of government action, the regulatory process, and government capacity. The seven sections of the strategy address key questions about the practice of regulation in Canada in the 21st century:

- How should we interact with other countries?
- How do we get our "national house" in order?
- How can we achieve better coordination within the federal government?
- How do we manage risks or hazards?
- What are the most appropriate tools or instruments?
- What is the optimal process for designing and implementing regulations?
- How does the government equip itself to deliver Smart Regulation?

The Committee notes that the elements of the strategy are highly interdependent. For example, the strategy calls for a more strategic approach to international regulatory cooperation, which will require more coordination among federal departments, improved federal-provincial-territorial cooperation and more flexible use of instruments. Conversely, improved international cooperation should enrich domestic risk management practices and strengthen and speed up the regulatory process.

As the policy environment continues to evolve, the Committee believes it is essential that the regulatory system become self-renewing — that the system is adapted on a continuous basis, as a result of lessons learned and results achieved, and becomes more responsive to new developments in science, business and society.

3.1 International Regulatory Cooperation

International regulatory cooperation involves looking outside the domestic toolkit to meet national policy objectives. Cooperation is increasingly important to achieving the key Canadian goals of providing high levels of consumer, social and environmental protection and promoting innovation, trade and investment. Cooperation can leverage international resources to address important regulatory issues of local, national and international concern. No country today can regulate well without using regulatory expertise from outside its borders.

International cooperation can take many forms. It can be the informal networking of officials, involvement in a multilateral working group to deal with a particular issue, or participation in an international standard-setting organization.

Activities include sharing information, undertaking collaborative scientific work, forging common data collection and risk assessment methods, carrying out joint reviews, and developing common or international standards.

Canada today is enmeshed in a dense web of international relations that govern many aspects of our lives. International standards provide the guidelines and benchmarks from which much of Canadian regulation is derived. There are standards for food safety, plant and animal health, biodiversity, transportation, emissions control, pharmaceuticals and toxins management, and safety standards for electric, medical and electronic devices. As new products are developed and new risks emerge, more and more international institutions are being formed to manage and mitigate harm.

Civil Aviation: The Role of Standards in Promoting Safety and Economic Growth

Civil aviation forms part of the economic and social lifeline of many countries, including Canada's. A plane takes flight somewhere in the world every few seconds. Flights are handled in a similar manner around the world. This uniformity is necessary for the safe and efficient travel of millions of people. Without international standards, air travel from one country to another would be impossible.

This precision in procedures and systems is made possible by the International Civil Aviation Organization (ICAO), whose mandate is to ensure the safe, efficient and orderly evolution of international civil aviation. The ICAO works with countries to develop universally accepted standards for civil aviation, including rules of the air, operation of aircrafts, air traffic services and environmental protection.

The ICAO is also the forum in which new standards are studied and negotiated.

International cooperation is increasingly important for building a competitive economy. Inefficient regulation inhibits trade, deters investment and hampers innovation. Different regulatory requirements between Canada and the United States, for example, can add to a company's design, production and administrative costs. These differences can dissuade foreign-based companies from developing or investing in the Canadian market, choosing instead to focus on larger, more lucrative U.S., European or Asian markets.

3.1.1 Key Challenges

Canada has been a strong and influential voice in developing and promoting the use of international standards since the 1950s. Its international activity is increasing over time. The Committee has observed, however, that much of this activity is ad hoc and uncoordinated. The result is an everything-is-important approach. Compounding this problem is the government's inability to accurately assess whether its international initiatives have helped to meet Canadian policy objectives. The situation raises a question as to whether the government's international regulatory activity is well aligned with national priorities and whether resources are being put to the best use.

Another key challenge is that, despite Canada's effort to cooperate internationally, significant regulatory differences remain between Canada and its key trading partners, particularly the United States. The cross-border movement of goods is still subject to an array of different regulatory requirements.

Coordination is an issue not only across federal departments, but between federal, provincial and territorial governments as well. There are many international standards in areas that are the sole or shared responsibility of provincial and territorial governments. It is important for federal regulators to collaborate with their provincial and territorial colleagues to ensure that international obligations and requirements are being met (see Section 3.2 "Federal-Provincial-Territorial Regulatory Cooperation").

3.1.2 Creating a Strategic Policy Framework for International Regulatory Cooperation

The Committee believes that international regulatory cooperation should be a distinct component of Canadian foreign policy. In support of this move, the federal government should develop a strategic policy framework for international regulatory cooperation. The framework should provide direction to departments on what Canada wants to achieve through international cooperation and how it intends to achieve it. The goal is to achieve high levels of environmental, health and consumer protection and support a dynamic economy. The framework should also identify priorities and key partners for international engagement.

The Committee believes that the framework should focus in the short term on the United States and North America, but it should also address other bilateral and multilateral cooperative arrangements within North America and internationally, and establish parameters for Canadian leadership abroad. The framework should be guided by the following principles:

- pursuit of the Canadian public interest through international engagement;
- simultaneous promotion of high levels of protection and economic competitiveness;
- provincial/territorial involvement in issues in their areas of responsibility; and
- transparency, accountability and public involvement.

The Committee proposes the following priorities:

- improving the management of threats to human and animal health and the environment;
- removing small regulatory differences that represent barriers to international trade;
- supporting investment in Canada in the research and development of new products;
- advancing international regulatory speed, predictability and consistency through the promotion of international standards; and
- promoting one review or joint reviews of new products to enter markets in multiple jurisdictions.

As part of the development of this framework, the federal government must be able to assess which international regulatory activities have yielded good results and which have not. It needs to systematically review and evaluate its international regulatory activities so that it can learn from and improve upon its experiences. Evaluating Canada's international cooperative initiatives will help the government pursue its priorities in those areas that are the most appropriate, particularly with regard to its efforts to remove regulatory barriers and promote joint reviews.

Recommendation 1: The federal government should include international regulatory cooperation as a distinct part of Canadian foreign policy. To this end, it should develop a strategic policy framework for international regulatory cooperation that identifies priorities for coordinated federal and national action. The framework should provide guidance in the following areas:
- **the design and implementation of regulation in Canada;**
- **an agenda for regulatory cooperation in North America; and**
- **Canada's key bilateral and multilateral relationships.**

Designing Canadian Regulation

As it pursues a more robust international regulatory cooperation agenda, the Committee believes the government should also limit the number of specific Canadian regulatory requirements. This step would reduce the cumulative impact of unique regulatory requirements on international commerce. This does not mean compromising Canada's ability to meet its social and environmental objectives. International cooperation does not mean lower standards. Rather, the emergence of global markets and the need to cooperate in managing international problems means that country-specific solutions are increasingly less effective. They are becoming a smaller and smaller percentage of the stock of regulations.

Canada should develop its own regulatory requirements only when they are necessary in order to meet national goals or values. In many cases, international standards are sufficiently developed that Canada can achieve its policy goals without the addition of Canada-specific requirements. In the few cases where there is no international consensus on a standard, if the approach of key trading partners meets Canadian standards for protection, their approach should be adopted.

There are some factors unique to Canada, such as climate and geography, that may require adjustments to international standards or the approaches of its trading partners. In the automotive industry, for example, Canadian vehicle safety needs are determined in large part by local factors including northern weather conditions, the Canadian road system and seat belt use rates.

To ensure that specific Canadian regulatory requirements are limited, departments should clearly state how these requirements are in the Canadian public interest. They should explain the intended results of the regulation and why these results are best achieved through legislative instruments. They should also demonstrate that these results outweigh the impact of the regulation on Canadian competitiveness and provide significant net benefits.

Recommendation 2: When developing new regulatory frameworks, the federal government should review and adopt international approaches wherever possible. The federal government should limit the number of specific Canadian regulatory requirements.

Recommendation 3: Specific Canadian regulatory requirements may be appropriate when:
- **there is no commonly agreed upon international or North American standard;**
- **important national priorities, unique Canadian circumstances or Constitutional values require different approaches; or**
- **the government does not have sufficient confidence that the regulatory processes, practices, results and/or decisions of a trading partner will meet Canadian policy objectives.**

Recommendation 4: Where specific Canadian regulatory requirements are adopted, the federal government should reduce or minimize the cumulative impact of regulatory differences on trade and investment by:

- **assessing alternative instruments for meeting policy objectives (e.g. voluntary measures, information strategies);**
- **promoting the use of performance-based approaches where possible; and**
- **establishing the appropriate accountability structures to review requirements regularly to ensure that policy objectives are being met and eliminate those regulations that are no longer necessary.**

Engaging Internationally

A) North American Cooperation

Free trade is a cornerstone of Canadian public policy. Since the signing of the Canada-U.S. Free Trade Agreement (FTA) in 1989, the two-way exchange of goods and services between Canada and the United States has more than doubled to $644.6 billion ($1.8 billion per day). Today, 79.7% of Canadian exports are destined for the United States.[2] Both the FTA and the North American Free Trade Agreement (NAFTA) focused on the movement of goods. More recently, there has been a shift towards services and technology, reflecting changes in the North American economies. NAFTA ushered in a new level of regulatory cooperation between Canada, the United States and Mexico. These three countries have set up several technical working groups to facilitate collaboration. But Canada still faces two significant challenges to improving regulatory performance and economic competitiveness.

First, Canada and the United States maintain parallel processes and structures across almost all areas of regulatory activity. Their two sets of processes reflect a convergence in policy objectives and regulatory procedures. However, much of this work is duplicative, particularly given the integrated North American market. The outcome can be poor regulatory and economic results and higher costs for governments, consumers and businesses, as illustrated in the sidebar on pesticides.

Regulating Pesticides in North America

The NAFTA Pesticides Technical Working Group has developed a coordinated pesticides regulatory framework for Canada, Mexico and the United States. The efforts of this working group led to the development of an option for joint regulatory approvals of pesticides between Canada and the U.S. Under the joint process, the U.S. Environmental Protection Agency and Health Canada's Pest Management Regulatory Agency each assess a portion of the application and then come to a joint decision. However, Canada undertakes a more stringent "efficacy" test (i.e. assessing whether the product performs as claimed) compared to the U.S.

The Committee has heard that the Canadian and/or joint process is perceived to be more burdensome than the U.S. process, leading some pesticide manufacturers to decide not to take advantage of the joint review and to seek approval for their products in the United States first. They sometimes decide not to seek approval in Canada at all.

Part of the challenge for industry and regulators alike stems from the small size of the Canadian pesticide market, which represents only 2% of world sales. Manufacturers may not want to risk any delay in access to the U.S. market that the Canadian process may cause. Further, the costs to obtain approval in Canada may make the Canadian market unprofitable to them.

As a result, U.S. farmers may get access to new pesticides that can be more effective or safer for human health and the environment than older ones on the market, and Canadian farmers do not, or they have to wait longer for them. The final result is compromised regulatory performance and dampened competitiveness for Canadian agriculture.

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[2] Department of Foreign Affairs and International Trade. *Fifth Annual Report on Canada's State of Trade*. March 2004. See http://www.dfait-maeci.gc.ca/eet/trade/state-of-trade-en.asp

Second, the cross-border movement of goods and services is still subject to an array of different regulatory requirements, a challenge the Public Policy Forum has called "the tyranny of small differences." Examples can be found in Part II, Section 1.1 "Manufacturing and Product Approval." Some of these regulatory variations arise from differences in policy objectives. But many of them relate to product classification, procedural requirements and decision-making processes without relevance to substantive results. As these differences proliferate, the cumulative impacts can significantly affect a company's ability to do business and, thus, can impede trade and investment.

The Committee believes that Canada must take a more deliberate and strategic approach to regulatory cooperation with NAFTA partners. Otherwise, it may face social, environmental and economic performance well below its potential.

The short-term objective is to achieve compatible standards and regulation in areas that would make the Canadian economy more efficient and provide high levels of protection for human health and the environment. It requires the removal of regulatory impediments to an integrated North American market and the elimination of the tyranny of small differences. Over the longer term, Canada should work with its NAFTA partners, particularly the United States, to build greater mutual understanding and trust in each other's regulatory processes and decisions, and create common or joint regulatory institutions or processes in key sectors.

The vast array of regulations in North America suggests that regulatory cooperation is a task that is best broken down into issue-specific segments. Such an approach makes it easier to bring together key partners, including provincial and territorial governments, First Nations, citizens' groups and industry leaders.

Stakeholders and federal departments have noted that it may at times be difficult to engage the United States in cooperative regulatory initiatives. In cases where regulatory differences are insignificant or present low risk, it may be in the public interest for Canada to be pragmatic and simply align its approach with that of the United States. The Committee believes that the smart approach, in these cases, is to avoid unnecessary duplication and focus regulatory resources on situations that warrant a unique Canadian solution.

Alignment may not be possible in areas where Canada-U.S. interests diverge and where there are significant policy differences. In these cases, measures should be put in place to reduce the impact of regulatory differences. They could include arrangements to share information, implement common data collection, risk assessment and decision-making procedures, and conduct joint reviews. A good example is the Four Corners Agreement negotiated in 1996 between Environment Canada, Health Canada and the U.S. Environmental Protection Agency (EPA) (for more details, see the sidebar on the Agreement). Similar mechanisms are in place for the joint review of pesticides.

Information-sharing and decision-making measures should be designed to help countries build confidence and trust in each other's regulatory and decision-making processes. They should also help us recognize that each country's regulatory standards, processes and decisions produce similar results. This recognition could eventually lead to one review and approval for a product to enter all jurisdictions in North America. Pesticides, animal vaccines and pharmaceuticals may be appropriate candidates for implementing single reviews for the North American market. (See Part II, Section 1.1 "Manufacturing and Product Approval.")

The United States will likely be interested in cooperative initiatives with Canada to achieve American social, economic and environmental objectives. The Committee believes that Canada and the United States should go beyond aligned regulatory frameworks and identify where they could move toward integrated regulatory institutions and processes. For example, integration is particularly important in those areas where environmental, economic and health issues converge with clean air, animal health and food safety issues. Given the integrated nature of the North American agricultural and food processing industries, Canadians and Americans could gain from having common risk management approaches, joint inspection and monitoring systems and joint emergency responses. Recent experiences with bovine spongiform encephalopathy (BSE) in both countries underscore this point. Similarly, Canada and the United States could collaborate to secure all ports of entry into North America to prevent the spread of risks to human and animal health and the environment. The goal of Canada-U.S. regulatory cooperation in these instances should be effective regulatory regimes that provide high levels of environmental, health and consumer protection.

Canada-U.S. Four Corners Agreement

Although Canada and the U.S. have different requirements for the review of new chemicals, they have recognized that it is not in the public interest for national agencies to duplicate each other's efforts. Environment Canada, Health Canada and the U.S. Environmental Protection Agency are cooperating to introduce new chemicals into the market more efficiently while assuring that public health and the environment are protected.

This cooperative relationship is embodied in the Canada-U.S. Four Corners Agreement. Under the Agreement, if a chemical is being reviewed in the United States, the company can request that the Agency share data and assessment findings with Canada. In return, Canada provides data to validate U.S. modeling tools.

Four Corners is a forum in which companies and governments work to eliminate barriers to regulatory cooperation. The partners envision a future where each country can understand and accept the other's decisions aimed at protecting human health and the environment, and where companies can submit one notification and then, after national review, market anywhere in North America.

Recommendation 5: North America should be the primary and immediate focus of the federal government's international regulatory cooperation efforts. The federal government should work to:

- **achieve compatible standards and regulation in areas that would enhance the efficiency of the Canadian economy and provide high levels of protection for human health and the environment;**
- **eliminate small regulatory differences and reduce regulatory impediments to an integrated North American market;**
- **move toward single review and approval of products and services for all jurisdictions in North America; and**
- **put in place integrated regulatory processes to support key integrated North American industries (e.g. energy, agriculture, food) and provide more effective responses to threats to human and animal health and the environment.**

Recommendation 6: The federal government should work with its U.S. and, where appropriate, Mexican counterparts to build mutual trust and confidence in each other's regulatory processes and decisions through the increased use of independent peer reviews of these regulatory processes, information sharing, shared data collection and risk assessment methods, common decision-making procedures and joint reviews.

B) Key Bilateral and Multilateral Relationships

While regulatory cooperation with the United States is of prime importance, Canada should not diminish its long-standing commitment to working with international standard-setting bodies and other jurisdictions. Broad-based international cooperation is essential in managing many, if not most, environmental and health issues today. It is also important to improving access to markets worldwide for Canadian exported goods and services. Europe and emerging markets such as China, India and Brazil are important markets for Canada to target.

Canada must continue to pursue targeted opportunities to work bilaterally with the European Union. The EU is the world's largest single market, having surpassed the United States in population and exports and rivaling it in gross domestic product. Following expansion in May 2004, its population has grown from 377 million to 450 million. Europe is Canada's second largest trading partner, receiving $33.6 billion worth of exports representing approximately 3.5% of Canada's GDP.

Canada's relationship with the European Union is strategic for more than just commercial reasons. The European Union is becoming an increasingly important regulation setter internationally, and both the European Union and its member states have undertaken several regulatory innovations and renewal efforts in recent years (e.g. the Better Regulation Task Force in the United Kingdom). The European Union can be a key ally for Canada in working towards international standards. When the standard is in the Canadian public interest, Canada should work with its European counterparts at bridging North American-EU differences.

At the December 2002 Canada-EU Summit, Canada and the European Commission agreed to "design a new type of forward-looking, wide-ranging bilateral Trade and Investment Enhancement Agreement (TIEA)" and "to intensify our regulatory dialogue and work toward a new framework in this field." The framework on regulatory cooperation will form the basis for developing voluntary cooperation between EU and Canadian regulators. Both agreements should be completed.

Working within international organizations also achieves the important objectives of improving international regulatory consistency and predictability through the development of international standards and common decision-making procedures. Common standards and procedures also help to reduce trade barriers and encourage investment.

The Committee believes that the federal government needs to focus its international regulatory activities on issues that derive the greatest benefit for Canada. A key area for multilateral cooperation is the approval of new and innovative products and technologies (see Part II, Section 1.2 "Biotechnology/Life Sciences"). For medium-sized countries like Canada, the ability to develop regulatory frameworks and evaluate every new product is a growing challenge. Canada should be a strong voice for the development of international standards for product safety and promote one review for products entering markets globally.

The single review of products requires high levels of trust in the decision-making procedures and processes of other jurisdictions. Trust is built through a process that involves exchanging information and collaborative scientific work, implementing common data collection and risk assessment methods, participating in joint reviews and monitoring performance through market audits, for example.

There may be cases where Canada should accept the decisions of regulators in other jurisdictions, particularly in the European Union and the United States, without undertaking a reciprocal confidence-building process and without compromising Canada's high standards for health, safety and the environment. The best candidates are products from areas where there are well-established, internationally recognized conformity assessment procedures already in place. In these cases, Canada should make arrangements with foreign regulators to review and monitor their decision-making procedures and regulatory performance.

Another key challenge for the federal government is to identify when Canada should be an instigator internationally. Canada may not derive any benefit from being the first country to establish a regulatory standard or framework in the absence of an international process or without the involvement of key partners. While exercising leadership is important, the government must be strategic and use resources for the maximum benefit of the Canadian public interest. Rather than being the first out of the gate with a regulatory framework, Canada should work bilaterally and multilaterally to reduce the differences that emerge across national regulatory systems in the absence of an international consensus. Enhancing international regulatory consistency and predictability can help reduce trade barriers and make Canada more attractive to investment in research and development. The government should focus on those areas where standards are necessary for the health and safety of Canadians, where Canada is a leading innovator and host to significant R&D investments, or where Canada has important national policy objectives to pursue.

The promotion of cultural diversity is an area where Canadian leadership has had a national and international impact. Following disputes with its trading partners, some of which it lost, Canada became a strong voice for clear ground rules to guide it and other countries in establishing regulatory frameworks to preserve and promote domestic cultures while respecting the rules of the international trading system. Canada's leadership in this area advanced the interests of federal and provincial governments and Canadian cultural groups. Canada's efforts were not intended to create unique regulatory requirements, but rather to promote international coherence and predictability. Canada should focus its future leadership efforts on areas identified as national priorities and as having significant innovation potential, such as biotechnology.

Culture and Canadian Leadership

Throughout the 1990s, the federal government's policies to protect and promote Canadian culture became the object of disagreements and formal trade disputes with Canada's trading partners. The reliability of the cultural exemption in free trade was called into question.

Consequently, Canada worked internationally to build support for the development of a multilateral convention. This convention would set out clear ground rules to enable Canada and other countries to maintain policies that promote their culture while respecting the rules of the international trading system. It would also be used as a point of reference and provide guidance to countries as they establish cultural policies and regulatory frameworks to preserve and promote domestic and local cultures.

To build a coalition of support, Canada established the International Network on Cultural Policy and worked with key state and NGO partners (e.g. Coalition of Cultural Diversity) in such forums as the Organization of American States and the Organization of La Francophonie. In October 2003, the UNESCO General Conference agreed by consensus to begin the process to develop a convention on the protection of the diversity of cultural contents and artistic expressions.

Recommendation 7: Canada should promote joint and single product reviews for multiple markets. Canada should also move toward accepting the approvals and reviews of products by its U.S. and EU trading partners in sectors where there are well-established, internationally recognized conformity assessment procedures already in place.

Recommendation 8: Canada should identify and target the areas where it wants to be an international leader, focusing on those areas that will produce maximum benefit for Canadian citizens and businesses, for example biotechnology, natural resource development and cultural diversity. 🍁

3.2 Federal-Provincial-Territorial Regulatory Cooperation

Federal and provincial/territorial governments in Canada share regulatory responsibilities in many areas, including agriculture, environment, food safety, pharmaceuticals and transport.[3] In the area of pharmaceuticals, for example, the federal government is responsible for approving drugs for market, and provincial governments regulate the selection of drugs used in each provincial medical system. Shared responsibility in a range of areas is enshrined in the Constitution. The problem is that the potential for duplication and inefficiency is high without careful coordination between the two orders of government.

Issues of overlapping jurisdiction and duplication have been raised in reviews of Canadian regulatory practice since at least the 1980s. The 1986 *Guiding Principles of Regulation* promised that the federal government would cooperate more with provinces to address "the overall regulatory burden" by eliminating "wasteful duplication." Following this review, provincial consultation was added as an element of the federal Regulatory Impact Assessment. In the 1990s, as part of further efforts to improve regulatory harmonization, federal and provincial/territorial governments signed the Agreement on Internal Trade and the Accord on Environmental Harmonization. During that decade, most provinces and territories also reformed their regulatory processes and eliminated thousands of outdated and unnecessary regulations.

Still, regulatory coordination between governments in Canada remains a serious problem. Stakeholders consulted for this report were unanimous in calling for major improvements in federal-provincial-territorial regulatory cooperation. Many noted that the absence of cooperation — both between federal and provincial/territorial governments and between provinces/territories — results in significant costs to the Canadian economy. The comment heard most often was that "Canada needs to get its national house in order" to create a stronger, more seamless national system and to improve international efforts.

3.2.1 Key Challenges

Lack of coordination between governments can seriously affect the efficiency and overall effectiveness of a regulatory system. The Committee's consultations and recent polling show that Canadians are increasingly frustrated and impatient with the lack of progress in this area. Non-cooperation increases costs and limits opportunities for both consumers and businesses. Industry representatives underscored that Canadian firms need a national regulatory system that is more predictable, timely and efficient if they are to succeed in a competitive international market. Firms are concerned about a persistent view abroad that Canada has an overly complex regulatory environment. This perception can be a deterrent to business development and investment in Canada.

Canadians Speak Out

In the 2003 edition of *Portraits of Canada*, 70% of Canadians identified improved federal-provincial-territorial cooperation as the second most important priority for government after health care. *Portraits of Canada* is the annual tracking poll conducted by the Centre for Research and Information on Canada.

Recent studies confirm these concerns and support the need for change. The 2002 review of regulatory reform in Canada by the Organisation for Economic Co-operation and Development (OECD), though complimentary overall, highlighted federal-provincial-territorial cooperation as a major priority for reform. The 2002 federal Innovation Strategy noted that different government regulatory regimes result in high compliance costs for business and constrain Canada's innovative potential. A report of key international corporate executives and foreign investors, prepared by Investment Partnerships Canada and released in 2003, identified coordination problems between orders of government in Canada as a key barrier to investment.

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[3] Municipal governments and some First Nations governments and institutions also have regulatory responsibilities; however, the Committee did not look into regulatory cooperation with municipalities. Regulatory issues with respect to First Nations are discussed at more length in Part II.

A significant challenge to addressing interjurisdictional coordination is the lack of a formal process and mechanism to promote cooperation. Federal-provincial-territorial ministerial councils have been established in most major policy areas (e.g. labour market, health, the environment and transport). But federal, provincial and territorial governments rarely meet to discuss regulatory policies. Government officials cautioned the Committee that simply creating another federal-provincial process is not the answer. They stressed that changing the status quo would require leadership at the highest levels and a clear mandate with priorities for reform.

Another challenge to federal-provincial-territorial cooperation, also identified in other parts of this report, is the lack of coordination between federal departments. This point was raised frequently in the Committee's discussions with provinces and territories. The Committee heard that cooperation with one federal department is often undermined by the actions of another.

Finally, the Committee notes that a common theme in discussions with stakeholders was the pressing need to accelerate implementation of the Agreement on Internal Trade. Provincial-territorial issues such as internal trade were outside the Committee's mandate. However, the Committee recognizes the significance of this issue for Canada and is encouraged to see internal trade on the agenda of the recently formed Council of the Federation.

3.2.2 Building Cooperation

The Committee believes strongly that a Smart Regulation regime will require governments to work together better. The Committee's vision and principles are not evident in the current arrangements between governments. As pointed out in the Committee's consultations, government stakeholders could help in the process to improve cooperation, as they have experience and insights into the barriers and areas of duplication that need to be addressed.

Further, the Committee believes that consistency within Canada is important to developing a more strategic international regulatory approach. As suggested in Section 3.1, provincial and territorial governments should be involved in developing new international approaches in areas that affect them. The current Action Research Roundtable on Canada-U.S. Relations, led by the Canada School of Public Service, shows that most provinces have developed close relations with individual American states in recent years across a range of areas.

An Innovative Cooperative Approach

Environment Canada and the Forest Products Association of Canada launched a Smart Regulation project in the fall of 2003 to explore options for a more cooperative approach to managing emissions from Canadian pulp and paper mills. They established a project team that includes experts from industry, the federal government, provincial governments and the environmental and Aboriginal communities. The project is intended to help build and maintain a strong, competitive and clean forest products sector in Canada. Its proponents will develop a national regulatory framework that builds on the emissions management architecture in the provinces, dovetails with industry's business planning cycle, provides more predictability and clarity, and stimulates innovative approaches to improving environmental performance.

The Committee supports the establishment of a more systematic approach to federal-provincial-territorial regulatory cooperation that also respects the distinct responsibilities of jurisdictions. That said, the status quo is not acceptable. The Committee agrees with those stakeholders who say that pragmatic, concrete solutions are needed that go beyond questions of jurisdiction. Indeed, some stakeholders suggested that serious consideration should be given to the substitution and delegation of regulatory responsibilities between governments and agencies. This idea may be worth exploring by federal and provincial/territorial governments.

The Committee believes there should be more information sharing between governments and learning from provincial/territorial regulatory innovation and best practices. To name just two examples that could hold important lessons for the federal government, the Government of British Columbia has implemented a Fast Track Approvals Process for projects (e.g. ski resort expansion) that aims to streamline regulatory processes, and the Government of Alberta is working cooperatively among departments to streamline and improve its energy, environmental and resource management regulatory regimes to efficiently protect environmental quality.

Promising Developments

The Committee notes some recent promising developments in regulatory cooperation. In March 2003, following the consultation report from the Innovation Strategy, federal-provincial-territorial deputy ministers responsible for innovation and trade established a working group on regulatory reform. Co-chaired by Industry Canada and the Province of British Columbia, the group identified best practices and guiding principles for reform and discussed possible priorities for future cooperation. It submitted its report to the Committee for consideration in January 2004.

SARS and Government Collaboration

In the October 2003 report, *Learning from SARS: Renewal of Public Health in Canada*, the National Advisory Committee on SARS and Public Health wrote: "...the single largest impediment to dealing successfully with future public health crises is the lack of a collaborative framework and ethos among different levels of government....The rules and norms for a seamless public health system must be sorted out in advance of a health emergency, with a spirit of partnership and shared commitment to the health of the citizenry, not on an ad hoc basis in the midst of the battle to contain a viral outbreak."

The report recommended two priorities for better collaboration: environmental assessments and biotechnology/emerging technologies. While cooperation agreements on environmental assessments have been signed between the federal government and a number of provinces and territories, consultations with industry, provinces and territories, and other stakeholders suggest that significant challenges remain. One key issue, for example, is the increased involvement of Aboriginal communities in these processes. As the second priority, biotechnology is seen as an example of an emerging technology with far-reaching implications for provincial and territorial governments. Their early involvement could improve the quality of regulatory decisions and implementation. Both priority areas are discussed in more detail in Part II.

The working group also suggested that it might be useful to pursue joint work in regulatory governance. A strong point of regulatory reform in Canada is the emerging practice of regulatory quality management: the development of policies, tools and institutions aimed at continuously improving the quality of the regulatory environment. This trend is consistent with that of OECD and APEC member countries. The OECD's work in this area points to significant benefits, such as improved economic performance, more effective and efficient government, and enhanced democratic values, such as transparency, public participation and responsiveness.

Early in the Committee's mandate, the Chair wrote to the most senior official in each provincial and territorial government and met with their representatives. These discussions confirmed a high level of interest among provinces and territories in collaborating on common regulatory issues. From these consultations, as well as discussions with industry representatives, First Nations and other stakeholders, the Committee believes that the timing and conditions are right for a broader and more sustained agenda of regulatory cooperation in Canada.

Recommendation 9: The federal government should pay urgent attention to creating a more seamless regulatory environment in Canada. Federal-provincial-territorial cooperation should be formalized in a new joint arrangement between governments, to be initiated through a discussion involving First Ministers. The new process should focus on key priorities (e.g. environmental assessments), identify and address impediments to cooperation, develop a framework to guide regulation making and publish regularly on the state of regulation in Canada.

Recommendation 10: The federal government should ensure the early involvement of provincial and territorial governments in developing Canadian positions on international regulatory issues that have an impact on their jurisdiction, and the two orders of government should work together to ensure the effective implementation of these international obligations.

Recommendation 11: Building on the report of the Federal-Provincial-Territorial Working Group on Regulatory Reform, the federal government should work with provincial and territorial governments on two priorities:

- **developing a common and consistent regulatory approach to environmental assessments. Given that environmental assessments often have an impact on Aboriginal communities,[4] federal and provincial/territorial governments should also involve Aboriginal peoples, where they have key interests; and**
- **exploring a cooperative approach to regulating in the area of biotechnology and emergent technologies.** ◆

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[4] 'Aboriginal' is used here to refer to people who self-identify as North American Indian, Inuit or Metis.

3.3 Federal Regulatory Coordination

Very few regulatory issues fall under the exclusive mandate of a single federal department. In the food processing sector, for example, there can be as many as three different federal departments and agencies with regulatory responsibility in this area — Health Canada, Environment Canada and the Canadian Food Inspection Agency (CFIA). This is in addition to Agriculture and Agri-Food Canada, which holds the broader policy responsibility for this sector.

Regulatees and other interested parties have expressed repeated frustration at having to deal simultaneously with different federal regulators with sometimes competing regulatory demands. This lack of regulatory coordination has a real impact in terms of increased production costs for industry. In addition, it contributes to a perception of Canada and Canadian regulation as being overly complex, which acts as a disincentive to investment in Canada. This multiplicity of federal regulators also creates barriers to citizens' participation in the regulatory process.

Lack of coordination has been acknowledged as an issue by senior federal officials, not only with respect to regulation but other aspects of government operations as well. It is referred to as the challenge of "horizontal management" and has been the focus of significant discussion and study.[5] Despite these efforts, however, not enough progress has been made and — to borrow the title of one of the studies on this topic — effective coordination among federal departments is still a "heroic act."

A constructive environment that supports increased regulatory coordination is essential to promoting economic growth and meeting regulatory objectives to protect health, safety and the environment and ensure a fair and efficient marketplace. The Committee believes that, if the federal government were better coordinated and spoke with one voice on regulatory issues, it would be in a stronger position to engage with international regulatory partners and work better with provincial and territorial governments and First Nations governments. Moreover, in showing its resolve to better coordinate its approach to regulation, the federal government would be more credible in promoting cooperation and the greater use of partnerships with industry and other stakeholders to advance public policy goals.

Fundamentally, the Committee advocates a cultural change within the federal public service, leading to a reformation by the government in how it develops, implements and enforces regulation. The Committee views the challenge of federal coordination as paramount to the Smart Regulation initiative and feels that, if progress can be made on this issue alone, it will greatly improve the regulatory landscape in Canada.

3.3.1 Key Challenges

One of the Committee's initial findings on this topic was that federal departments still work predominantly in "silos," meaning within the monopoly of their legal mandate and expertise. This approach results in regulation that is used to advance only a narrow departmental mandate, rather than government-wide social, environmental and economic priorities as well. The Committee believes that this is a key barrier to overcome. Regulatory officers should not feel that they are compromising the regulatory mandate of their department because they are also considering the achievement of broader national objectives.

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[5] For example, a number of studies on this topic have been commissioned in recent years. Please see: Herman Bakvis and Luc Juillet, *The Horizontality Challenge: Line Departments, Central Agencies and Leadership*. Canada School of Public Service, 2004; Jacques Bourgault and Rene Lapierre, *Horizontality and Public Management*. Canadian Centre for Management Development (CCMD), 2000; Mark Hopkins, Chantal Couture and Elizabeth Moore, *Moving from the Heroic to the Everyday: Lessons Learned from Guiding Horizontal Projects*. CCMD Roundtable on the Management of Horizontal Initiatives, James Lahey (Chair), 2001.

A second major challenge to federal coordination lies within the government infrastructure itself. The Committee has noted a lack of mechanisms within the government to ensure that regulatory coordination among departments occurs and is made easier. There is no locus within the government to facilitate interdepartmental coordination on regulatory issues — particularly when various departments may hold conflicting views on the same issue — and to ensure that regulation is aligned to advance government priorities. As noted in a 2004 report by the Canada School for Public Service, there is a "failure to realize that departments had only a limited capacity to overcome interdepartmental differences" and that there might be a role for central agencies "with respect to initiating, sustaining, resourcing, coordinating, and monitoring horizontal initiatives."[6]

The third major observation made by the Committee is the absence of clear policy and strategic directions on many fronts. The Committee makes many recommendations in this regard throughout the report, particularly in Section 3.1 "International Regulatory Cooperation" and Part II, Section 1.5 "Oil and Gas Exploration and Development." Horizontal management has often been reduced to a process (i.e. the creation of an interdepartmental committee) rather than a means to achieve collective objectives. Without substantive direction, these processes generate considerable frustration for the participants and observers of the process, not to mention those whom it is supposed to serve.

3.3.2 Mechanisms for Coordination

Given the diverse nature of their respective mandates, federal departments sometimes have different or conflicting views on the same regulatory issue. The result is that the government does not speak with one voice on issues when dealing with industry or other interested parties. The Committee has witnessed this phenomenon first-hand, as various departments have presented conflicting views on specific regulatory issues to the Committee throughout the process of preparing this report.

While Memoranda to Cabinet require interdepartmental consultation in order to develop a consensus on a given policy issue, this coordination does not necessarily carry through to the development and implementation of regulations. As discussed earlier, "horizontal management" in the federal public service "is still at a pioneering stage . . . too frequently it seems managers must overcome obstacles that the 'system' could reduce or eliminate."[7] As such, the Committee recognizes that departments need a place where they can discuss, debate and develop a joint position on a specific regulatory issue.

The Committee notes that the Government of Canada's Regulatory Process Management Standards require that the development of new regulations involve interdepartmental coordination to "determine what, if any, related regulatory requirements already exist." The standards also require that "new regulatory requirements must be coordinated with existing ones to avoid duplication and to take advantage of possible efficiencies."[8] Despite these requirements, the Committee has heard that, in practice, the department that holds the regulatory authority has the *discretion* to consult with other departments on regulatory issues, rather than consultation occurring systematically.

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[6] Herman Bakvis and Luc Juillet, *The Horizontal Challenge: Line Departments, Central Agencies and Leadership*, pp. 2-3.

[7] Mark Hopkins, Chantal Couture and Elizabeth Moore, Moving from the Heroic to the Everyday: *Lessons Learned from Guiding Horizontal Projects*, p. v.

[8] Privy Council Office, *Government of Canada Regulatory Policy*, November 1999, p. 11.

The Committee feels that this approach is unsatisfactory and does not go far enough. Instead, the process or mechanism envisaged by the Committee would ensure that all departments that have an interest in a regulatory issue are involved, as appropriate, whether in policy development, the development of regulations and the administration of regulatory programs, or the enforcement and evaluation of these regulations. What is required is a process or mechanism for departments to come together to discuss and debate regulatory issues, including the impact or relevance of ongoing regulation and the creation of new regulations. It is the position of this Committee that this coordination function should be played by the Privy Council Office (PCO), as it is the central agency responsible for regulation.

> **Recommendation 12: The Privy Council Office should establish a mechanism to support interdepartmental discussion and foster the development of government-wide positions on regulatory issues and ensure that departments take appropriate action to align regulations with national priorities.**

3.3.3 Policy Frameworks

Regulatory coordination would be greatly facilitated by the provision of clear, consistently applied policy directions to allow for coherent regulatory decisions across government. Policy frameworks would be used to coordinate regulation by several federal departments clustered around certain activities or sectors. This could involve a general regulatory area, such as departments' involvement in international regulatory cooperation, or a specific sector, such as regulatory activity in natural resource development in Canada's North. By articulating the government's broader policy goals, policy frameworks would be able to provide guidance to regulatory authorities — with concrete objectives and standards to gauge success — and would provide long-term coherence to governance in a given area.

Policy frameworks could also focus on accountability and the need for departments to follow through on implementation, including at the regional level. The Committee heard that policy frameworks would help to reduce the inconsistent enforcement of policy and regulation by federal regional offices across Canada (this achievement would be particularly helpful with respect to the environmental assessment process). In addition, the Committee feels that policy guidance at the regional level must be complemented by strong accountability in regions and leadership by headquarters.

> **Recommendation 13: Overarching regulatory policy frameworks should be developed that spell out the government's objectives in a sector or area of regulation. These frameworks would provide overall guidance to the various regulatory authorities and ensure that regulatory action is coherent and integrated. For example, policy frameworks should be established for sectors such as biotechnology and issues such as international regulatory cooperation.**

3.3.4 Single Windows and Federal Coordinators

Industry and NGOs alike have cited the lack of single windows to engage with the federal government on the regulation of a given issue or sector. As demonstrated by the food processing sector, there could be myriad federal organizations — and even a number of contact points within each department — for stakeholders to deal with. This occurrence is particularly daunting for the individual citizen or small or medium-sized business that wishes to participate in the regulatory process but does not possess the legal or financial resources to navigate the system to ensure compliance with federal regulations.

The use of single windows on specific regulatory issues (e.g. environmental assessments) or at the industry sector level (e.g. the automotive industry) would be a significant and necessary step to improve coordination. By "single window," the Committee refers to a single point of contact for the entire federal government to liaise with a specific industry sector. This approach should be complemented by the use of e-government in order to ensure all of the necessary regulatory documentation is available online and is easy to use.

Moreover, the Committee feels that the use of single windows at the federal level could eventually lead to a leadership role for the federal government in working with other orders of government to create single window service on specific issues for all of Canada, as appropriate.

Single windows should be complemented by the appointment of federal coordinators for specific large-scale investment projects, such as the Mackenzie Gas Pipeline (MGP) project. A federal coordinator would be given clear decision-making authority and accountability with respect to the relevant federal departments in order to establish an efficient and transparent regulatory decision-making process for each respective project. This federal coordinator would also ensure that the federal government speaks with one voice when engaging with other jurisdictions, stakeholders and interveners on the project. Both the single window and federal coordinator approaches would significantly reduce transaction costs for stakeholders and governments. Some of these issues are discussed at greater length in Part II.

Recommendation 14: The federal government should provide stakeholders and the public with single window access. It should also take a leadership role in working with other orders of government to create single window service.

Recommendation 15: In the case of significant investment projects, the federal government should designate coordinators with the appropriate decision-making authority to oversee the regulatory involvement of various federal departments. ♣

3.4 Risk Management

Regulators need to act on problems or risks even in the face of uncertainty and imperfect information. Because their resources are limited and the number of issues they could address is almost infinite, they need to make hard choices about priorities, types of intervention and the commitment of resources. At the same time, citizens are demanding ever-greater levels of protection against an expanding range of potential hazards, and industry is asking for a predictable business environment. Regulators therefore need a process for solving problems and making decisions in a principled, consistent and transparent manner.

At the centre of risk management is the idea that a rational, deliberative and evidence-based approach to decision making will deliver better results over time. It recognizes that risk cannot be eliminated totally, but it can be managed in such a way as to mitigate or reduce harm to the greatest extent possible and practical.

What is Risk Management?

Risk management is a systematic approach to setting the best course of action under uncertainty by identifying, understanding, assessing, prioritizing, acting on and communicating about potential threats, whether they affect the public's social, financial or economic well-being, health and safety, or the environment. Managing the related risk involves allocating limited national resources where they can do the most good for the greatest number of people. It includes the following steps: identification of the issue; assessment of the level and severity of risk; development of the options; decision; implementation of the decision; and evaluation and review of the decision. At each step of the process, communications and consultation activities, legal considerations and ongoing operational activities must also be taken into account in effective risk management strategies.

Expanding knowledge and technical competence, combined with rapidly and widely disseminated information about real and perceived risks, means that the function of risk management has become more important for regulators, particularly those working in science-based regulatory regimes. The Committee believes that taking a risk management approach in the design of regulations and the administration and enforcement of regulatory programs must be an essential component of a Smart Regulation strategy.

The examples used in this section relate essentially to science-based regulation (e.g. health and safety and the environment). Risk management is relevant for all regulatory programs; thus the proposed approach could be applied to other fields.

3.4.1 Key Challenges

Regulators must make decisions in an environment characterized by complexity, uncertainty and imperfect information (see Table 3.1). The issues they address are increasingly interrelated and international in nature. For example, ensuring the safety of the North American food supply requires consideration of several factors, including the effects of chemicals and biotechnology on human health and the environment, international trade flows, and manufacturing and labeling practices. This challenge is compounded by the fact that risks can often have both beneficial and harmful consequences. Take, for instance, the development of a new therapeutic product. The availability of this product can lead to important improvements in the health and quality of life of many individuals. However, the manufacture and disposal of the product may have harmful effects on the environment that need to be managed and regulated.

Another challenge for regulators is that risk does not respect departmental boundaries. An integrated approach to risk management is therefore required to protect the public interest. Coordination is critical when the policy and regulatory responsibilities for an area such as agriculture and food issues are shared

Table 3.1 Risk-related issues and the regulatory environment

Citizens' Perception of Risk		**Risk-Related Issues**	**Current Examples**
	New Technologies	Risks arising from new and emerging industries	Aquaculture, genetically modified organisms (GMOs)
		Risks arising from products on the market	Adverse drug reactions
		Risks arising from new processes	The impact of refrigeration and the use of CFCs on the environment
	International Sources of Risk	The rapid international spread of threats to human health and the environment	Severe Acute Respiratory Syndrome, the spread of invasive species, West Nile virus
		International impacts of industrial and agricultural activities and trade	Climate change, ozone depletion, high toxicity levels in the Canadian Arctic, air traffic control
	Better Understanding of Risk Trade-offs	A better understanding of how reducing some risks can increase others	Chlorine in the drinking water reduces risks from biologic hazards, but may pose a small extra risk of cancer.
			Fuel efficiency standards reduce environmental harm from emissions, but may increase risks of traffic fatalities and injuries as cars become lighter.
			The approval process for drugs and medical devices reduces the risk that dangerous products will be marketed, but may delay the time-to-market of products that save lives.
	New Ways of Managing Risks	New legislative frameworks identifying risks that need to be managed through regulation	*Species at Risk Act; Oceans Act; Canadian Environmental Protection Act, 1999; Pest Control Products Act*
		Managing risks through partnerships	Shift in emphasis from direct market intervention to consumer protection
		Government shift from the use of economic to social forms of regulation	
	Scientific Breakthroughs and Technological Advances	Scientific discovery of new risks leads to changed risk perceptions and new demands on government	Discovery of mercury in fish products, the linking of bovine spongiform encephalopathy to Creutzfeldt-Jakob Disease
		Better techniques of detection and measurement bring to light new risks	Discovery of endocrine disrupters in drinking water arising from the use of pharmaceutical products
		Scientific advancements that can lead to the emergence of new industries	Stem cell research, reproductive technologies, nanotechnology

among multiple departments (e.g. Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Health Canada and Environment Canada). In such instances, the government should have in place coordinated approaches to scanning, assessing and comparing risks as well as implementing and evaluating policy and related regulatory programs.

Some issues may also require the involvement of provincial and territorial governments. Improving water quality and safety in Canada, for example, requires the coordinated efforts of at least five federal departments and the provincial and territorial governments.

Another challenge concerns the transparency of decision making and public perceptions of risk. Individuals have a different relationship to risk than governments. They tend to focus on more personal factors, such as the potential consequences of harm or injury to themselves, family members and friends. Citizens also want to make their own decisions about many risks, such as transport and food choices, and regulators must make sure that people have access to information on the inherent risks of various decisions. Regulators cannot simply decide behind closed doors what is in the best interest of citizens. They should be transparent in their decision making and involve citizens in a meaningful way. The regulator's ability to communicate with and engage citizens and other parties is a critical success factor in sustaining trust in the regulatory system.

Recent Risk Management Initiatives in Canada

The Government of Canada has recognized the contribution of risk management to a modern regulatory system. Since the release of the report *Risk Management for Canada and Canadians* in 2000, the government has made significant progress in this area. Several initiatives have followed this report to address specific, risk-related issues such as precaution, resource allocation, risk assessments and risk communication as well as legal risk. These initiatives have created significant awareness and encouraged the practice of risk management in the federal government. Future efforts should recognize and build on this work, which includes:

- The Treasury Board Secretariat's *Integrated Risk Management Framework* (2001)
- The Treasury Board Secretariat's *Integrated Risk Management Implementation Guide* (2004)
- The Privy Council Office's *Framework for the Application of Precaution in Science-Based Decision Making About Risk* (2003)
- Health Canada's *Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (2000)
- The Department of Justice's co-lead with Treasury Board in the current Legal Risk Management (LRM) initiative (launched in early 2000)
- The Canadian Food Inspection Agency's *Risk Communication and Government: Theory & Application for the CFIA* (2001)

3.4.2 Risk Management Framework for Regulation

The Committee believes that the federal government should develop a risk management framework for regulation that would serve as a guide for departments when they prepare specific risk management approaches. It would provide guidance to regulatory officers so that their decisions are made within a transparent framework and are not subject to their personal evaluation of risk. A framework helps regulators conduct rigorous analysis, exercise sound judgment and, ultimately, make decisions in the face of uncertain hazards.

The Committee believes that departments should be more consistent in their approach to risk management, recognizing that different risks will require different management strategies. For each regulatory program, for example, risk should be classified in terms of severity and anticipated response (e.g. the use of different instruments), including thresholds of risk below which government will not intervene through regulation. Proportionately greater attention and resources should be devoted to risks identified as high departmental or governmental priorities. Lower-level risks should be approached through less resource-intensive compliance mechanisms (e.g. information programs). This classification should be reviewed systematically to take into account new science, changing behaviors and results achieved through the programs.

Departments could take a consistent approach to risk by developing and adopting a risk management standard such as the Canadian Standards Association's Q-850 (see sidebar). A good model is the risk priority matrix developed by Fisheries and Oceans Canada that determines thresholds for various types of regulatory action. Such a framework is broadly applicable to a range of regulatory issues (see Part II, Section 1.4 "The Environmental Assessment Process").

The risk management framework for regulation should include three core elements: risk prioritization, risk assessment, and risk communication and consultations.

Key objectives of this framework are to:

- reduce the risk of harm through effective and responsive regulation;
- allocate and prioritize departmental resources to provide the greatest benefits at the lowest cost;
- ensure that the risk management process becomes more transparent, consistent across departments and predictable;
- improve expectations, mutual understanding and trust among industry, government and citizens;
- ensure that risk assessments are evidence based;
- achieve government-wide shared practices for risk management that emphasize strategic risk prioritization and forecasting, ensure that regulatory measures are commensurate with the risk involved, and make use of a mix of instruments (for enforcement and compliance strategies as well);
- develop innovative opportunities for public participation in determining risk priorities and levels of protection; and
- respond better to risk management problems that involve more than one department.

Risk Management Standards – The Q-850 Model

Business relies on a predictable, transparent regulatory environment, and citizens can make better personal decisions if they understand risk management well. Risk thinking and frameworks applied in the private sector have only begun to be reflected in government, notably at Transport Canada.

The Canadian Standards Association's Q-850 model sets out a six-step sequence that includes the identification of an initial problem or opportunity, preliminary analysis, risk estimation, risk evaluation, risk control and action/monitoring. Risk models that are already used by business, like the Q-850, provide an excellent vehicle for leveraging the shared risk management responsibilities between government, business and citizens.

Health Canada applies the *Decision Making Framework for Identifying, Assessing and Managing Health Risks* (2000), while the CFIA has developed the *Risk Analysis Framework to address Animal Health, Plant Health and Food Safety Risks within the Canadian Food Inspection Agency* (2003). Both models mirror the Q-850 principles.

Recommendation 16: The federal government should develop a risk management framework for regulation that would include the three following core elements: risk prioritization, risk assessment, and risk communication and consultation.

Risk Prioritization

Canada has limited resources to achieve a growing range of public policy objectives; at the same time, the regulatory environment is driven by greater public demand for accountability and fiscal responsibility. It is therefore critical for government to apply risk management when deciding how to allocate regulatory resources. Resources should be allocated to achieve the greatest social and environmental benefits in the most cost-effective way.

Some departments have begun to develop risk profiles — taking into account a range of political, social, legal and financial factors — related to the effective use of resources to manage risk.

A Risk-Based Approach to Planning, Operations and Performance Measurement – The Canadian Food Inspection Agency

The Agency is the largest federal science-based regulator responsible for delivering federal inspection, certification and quarantine services for the food, animal and plant sectors. The CFIA regulates over 4,000 domestic food processing establishments, hundreds of thousands of domestic shipments of live animals, plant and forestry products, and approximately $70 billion in annual import-export trade.

In recent years, the Agency began a process to make its regulatory activities more effective by incorporating risk management principles into its strategic and operational planning and control systems. Science-based risk management principles that were applied at a sector-by-sector level are now being applied strategically across all programs through an integrated risk-based planning, operating and reporting system.

The basis of the system is a Corporate Risk Profile which quantifies the risk (likelihood and consequence), assesses the mitigation strategy in place to manage the risk and identifies the residual risk and risk tolerance associated with each of the Agency's strategic outcomes. Based on the outcome of this process, strategic work plans are created, and a performance management system provides managers with feedback on the results being achieved.

Applying risk management principles at the strategic planning and operational levels provides Agency management with an increased level of assurance that risks are identified, assessed and considered in a comprehensive and proactive manner.

Risk identification and the evaluation of priorities should be done consistently — from both a departmental and a whole-of-government perspective. Risks often need to be managed by more than one department, and risk reduction activities in one area increasingly have the potential to increase risks in another.

Risk scanning should be performed on an interdisciplinary basis in order to leverage and pool knowledge and regulatory capacity. In addition to all relevant government officials, the activities could involve Canadian and international scientists from research institutions and academia, provincial and territorial governments, regulatory officers from other countries, industry representatives, non-governmental organizations, citizens' groups and think-tanks.

Regulators should establish their risk priorities, which should be made public, as well as their rationale for choosing these priorities. Departments' annual reports on plans and priorities should present the corresponding resource allocation, and departmental performance reports could highlight the progress made towards reducing these risk priorities.

> **Recommendation 17: The federal government should undertake periodic risk scanning exercises and ensure that regulatory programs and resources are allocated to address Canada's risk priorities.**

Risk Assessment

Regulators must develop a deep understanding of the nature of the problem or hazard they need to address. This means undertaking the necessary research and analytical work and measuring and quantifying the risk at stake. Science is critical to informing the development of regulatory options and decisions, from policy to enforcement and should be conducted in an independent manner and peer reviewed when necessary. This is a key step in the risk management process that provides a strong evidence-based foundation for risk assessment.

In science-based regulation, it is essential that risk assessors have access to the best and latest science to make sure that the regulation reflects leading-edge knowledge. At a time when knowledge is evolving very quickly, this is no easy task. Further, maintaining sufficient in-house scientific capacity and other professional expertise to ensure that risk assessments are based on adequate data and independent research is crucial for government. There should be regular monitoring of government scientific capacity to ensure that the science base is adequate. Periodically, an independent scientific institution could be asked to undertake such a review. Attracting and retaining respected scientists in government will represent an ongoing challenge, given the competition for scientific talent that exists among potential employers.

As argued in the section on international regulatory cooperation, regulators must also maintain relationships and share information with their colleagues in other countries and access international scientific networks. Increased collaboration should be established with the Canadian scientific community (e.g. the National Research Council of Canada, the Canadian Institute for Health Research and universities) on regulation in general and risk assessment in particular.

In addition to scientific information, regulators must also understand the public environment. In developing a regulatory response, they must take into account issues such as values, public tolerance to risk, policy priorities and the evolving social, cultural, political and financial environment.

There are currently no federal risk assessment standards or guidelines. As a result, government as a whole is inconsistent in performing risk assessments that explicitly and transparently describe how empirical evidence and the public environment inform and influence regulatory decisions and serve the public interest. This difficulty is compounded by the fact that, as indicated earlier, risk increasingly needs to be assessed from an interdepartmental perspective. Departments have not yet adopted a coordinated strategy for risk assessments that would allow them to better address new sources of risk to health, safety and the environment and set priorities, particularly when the risk cuts across many departments. Measures to improve consistency and coordination among departments would be desirable.

Precaution

It is important to ground regulatory decisions in science. However, when regulators cannot count on full scientific certainty and they need to make a decision because there is a risk of serious or irreversible harm, they will apply "precaution." The use of precaution is prescribed in several key pieces of Canadian legislation, including the *Canadian Environmental Protection Act, 1999* (also known as CEPA 1999), the *Species at Risk Act* and the *Oceans Act*.

On a day-to-day basis, regulatory officers or inspectors use precautionary considerations in making decisions. It is part of the regulators' responsibility to anticipate problems and prevent them from occurring. Applying the principle of precaution can be in the public interest and consistent with a Smart Regulation approach. At the same time, the manner in which precaution is integrated in risk decision making is important. If the application of precaution is abused, it can increase risks and impose unnecessary costs on all those involved in the regulatory system, including governments. The *Framework for the Application of Precaution in Science-based Decision Making about Risk*, recently developed under the leadership of the Privy Council Office, represents a solid foundation to frame the government's use of precaution. It will be important for departments to explain how they will implement this new policy.

The Committee sees no need to formalize precaution in the vast majority of day-to-day circumstances where there is little scientific uncertainty. However, there are situations (see the sidebar on the New Directions Group) that warrant the framing and establishment of specific processes for the application of precaution.

Addressing these special situations will often call for increased engagement from interested parties, including industry and non-governmental organizations. Some feel that such a process delays decision making. The Committee believes that, when based on cooperation and a commitment to finding solutions, the involvement of many parties can improve the timeliness of decisions, contribute to maintaining trust in the regulatory system, and ensure that protection objectives are met and that innovation is not stifled. Transparency and accountability should guide these processes.

Precaution decisions should be grounded in the best available science. Addressing these situations will often necessitate increased information and additional reviews. Other countries often rely on a national science academy to provide scientific advice to the government in these circumstances. In the absence of such an institution in Canada, it would be desirable to involve peer reviews, both with Canadian and international experts, when the precautionary principle is used to justify a significant regulatory action.

New Directions Group Report

In March 2004, the New Directions Group, which comprises experts and environmental leaders from Canadian businesses and non-governmental organizations, released its report, *Applying Precaution in Environmental Decision-making in Canada*. It proposes an architecture for applying precaution in risk-based decision-making processes which varies according to the level of scientific uncertainty, the potential risk and the ability of the policy and regulatory regime to handle the issues. It proposes that most decisions would fall under a "standard risk assessment/risk management process," incorporating precaution. When the potential risks or benefits to society are considerable and the level of scientific uncertainty high, it favors a process with enhanced stakeholder involvement in decision making. It argues that an alternative decision-making process should be established in the following very rare instances: when there is a significant lack of societal consensus due to a clash of values; when there is a considerable amount of scientific uncertainty and/or controversy and potential risk; and when the policy or regulatory framework is unclear or inadequate or no regulatory authority is willing to assume responsibility for the process.

Decisions resulting from these processes should be periodically reviewed as science evolves, new knowledge is generated and the public environment changes.

Recommendation 18: The federal government should develop a federal risk assessment standard or guidelines for regulation that would include:

- **a federal strategy to systematically and strategically access the best scientific information and knowledge to support regulatory decisions;**
- **the coordination of risk assessments across departments;**
- **the classification and prioritization of risks, including the identification and publication of the risk priorities of each regulatory department;**
- **regular scanning of the public policy environment;**
- **systematic re-evaluation of these risk priorities in order to account for advances in information and science, results accomplished by the regulatory programs and changes in the public environment, and to respond to new sources of risk; and**
- **a regular review of the government's scientific capacity.**

Recommendation 19: Federal departments should frame and establish processes for the application of precaution in specific situations, such as when the potential risks or benefits to society are a high priority; when the level of scientific uncertainty is high; when there is a significant lack of societal consensus due to a fundamental clash of values; or when the regulatory framework is unclear or inadequate for addressing new emerging risks. For these situations, they should:

- **develop protocols and processes for decision making and how they plan to use precaution in decision making;**
- **explain the rationale for the use of the precautionary principle to the public;**
- **consider independent peer reviews to assess the rationale for acting rather than waiting for more evidence; and**
- **commit to the regular review of significant decisions based on the precautionary principle to determine if information has become available that is relevant to the decision.**

Risk Communication and Consultation

It is not possible for government to protect the public from all forms of harm. For example, pesticides make fruits and vegetables more affordable and accessible, and these foods in turn lower many health risks, such as certain types of cancer. However, pesticides may increase other cancer risks. One challenge that regulators face in implementing risk management regimes is the difficulty that citizens and parliamentarians have in understanding certain risk trade-offs. This is particularly true when a situation is perceived to be a regulatory failure (e.g. the withdrawal of a drug from the market). Such outcomes often lead to increased — and not always rational — calls for regulatory intervention.

The Committee believes that risk management must be recognized as a task in which government, industry and citizens play complementary roles to bring risks to acceptable, manageable levels. A critical success factor of a Smart Regulation strategy is government's ability to communicate effectively about risk and to engage citizens, media and parliamentarians in how to manage it. Risk communication plays a key role in establishing trust in Canadian markets and institutions. It is worth noting that a proactive and cooperative communication strategy regarding the BSE incident in the summer of 2003 contributed to maintaining the trust of Canadian citizens, who increased their beef consumption.

Uncertainty concerning sources of harm can be addressed through good professional judgment and action on the part of regulators. At the same time, public trust can be maintained and enhanced by rendering uncertainties transparent. A transparent regulatory system also contributes to increasing the predictability of the business environment, which is something industry values highly. It is therefore important for regulators to clearly explain their decisions, including the factors they analyzed and the options they considered.

Public consultations are critical because risk management is more effective when government works with citizens and industry. Government cannot manage risk alone. Public engagement complements peer-reviewed scientific, economic and social analyses. Citizens and industry have important roles to play in identifying and evaluating priorities, risk tolerance levels and appropriate government and industry responses. Regulators need to find new and innovative ways to engage citizens in order to better understand their risk tolerance, and to obtain their input on risk priorities, risk management options and the corresponding allocation of regulatory resources.

The fast pace of scientific development and the trend towards increased access to information can lead to a more confused citizenry. For example, for years physicians told their patients that cholesterol was bad and that they should avoid it in their diet. Now scientists tell us that there is "good" cholesterol as well, which makes food choices more complicated. Citizens do not always know whom to believe and where to find accurate and independent information. One of the roles of government as a risk manager is to ensure that citizens have access to relevant information to help them make choices.

Recommendation 20: The federal government should develop and publish federal guidelines for risk communication that provide:

- **a clear and transparent explanation of the rationale for decisions and how they were made, including the relative weight assigned to the various factors used in decision making; and**
- **a strengthened role for the federal government as a reliable provider of scientific and other relevant information to consumers, parliamentarians and the media.**

Recommendation 21: The federal government should develop guidelines on how public engagement could be used to gain a better understanding of public risk tolerance and to obtain input into key risk management issues and options. ◆

3.5 Instruments for Government Action

Governments have a broad range of instruments or tools to help them achieve their policy objectives. In addition to the more conventional legislative instruments are performance-based regulations, economic instruments, information and education programs, voluntary initiatives and standards, to name just a few. Each instrument involves stakeholder cooperation to varying degrees, such as industry in the case of voluntary codes, and each has its own merits and limitations.

EnerGuide Labeling Program

The Office of Energy Efficiency operates the EnerGuide labeling program, which aims to protect consumers against exaggerated energy conservation claims made by manufacturers of energy-using equipment. The statutory basis for the program is found in the *Energy Efficiency Act* and its regulations, which set out minimum energy-efficiency standards for a range of energy-using equipment and provide for mandatory testing and third-party verification of this equipment. The EnerGuide label is mandatory for appliances, but it is an industry-led initiative for major heating and cooling products. Industry manages the labeling process and engages its members to provide an EnerGuide rating in brochures and to provide market information to Natural Resources Canada. Promotion is done by the department and industry.

The Committee recognizes the benefits of using a mix of instruments. This approach allows the regulator to adapt its intervention to the circumstances at hand and to draw on the strengths of the most appropriate tools. In some cases, well-designed conventional regulatory approaches may be the most efficient and effective, especially when accompanied by compliance, promotion and other supportive programs. In other cases, there may be advantages to using alternative instruments, sometimes as stand-alone initiatives and in other situations as supplements to conventional approaches.

For example, a study conducted by the Department of Justice on its impaired driving initiative indicated that, while legislation was necessary, changing people's attitudes through outreach and education (as in the case of Mothers Against Drunk Driving) was also essential to reducing the incidence of drinking and driving.

3.5.1 Key Challenges

For most of the last century, regulatory practice has relied heavily on a command-and-control model, which focuses on rules to determine behaviour in the hope of producing desired outcomes. Despite the federal government's efforts to encourage departments to consider and use a broader variety of alternative instruments, by training federal officials for example, progress in this area has been slow. Departments still rely too heavily on laws as their tools of choice, without giving due consideration to other options. This is particularly true for economic instruments, which are addressed at the end of this section. The Committee would also like to see greater use of performance-based regulation.

At this time, lack of awareness and experience remain barriers to the increased consideration and use of a broader variety of alternative instruments. Another challenge stems from the fact that the federal government has not yet framed the use of instruments to assist regulators, especially those who design and implement enforcement and compliance strategies. There is no framework to serve as a road map and there is little debate on, or ongoing challenge of, instrument decisions, including whether or not to regulate in the first place. Without clear government guidance, officials involved in regulation (e.g. lawyers, policy analysts, regulatory officers) must rely on their experience and expertise to make instrument decisions and they have little incentive to innovate. Further, legislative constraints on creating and implementing mixes of instruments were raised as a key challenge to the greater use of alternative instruments.

Moreover, in some cases, non-existent or unclear policy direction and objectives also create a barrier to the proper consideration and use of alternative instruments. The Committee recognizes that without clear goals, the effective consideration and assessment of potential instruments and the design of optimal instrument mixes become significantly more difficult. This objective is further hindered by the potential for instrument discussions to turn into policy discussions.

The Committee also observed that concerns over effectiveness posed another challenge to designing and implementing a variety of innovative alternative instruments. During its consultations, it noted that NGOs and citizens still perceive and trust the government to be the "guardian" that protects their health and safety as well as the environment. A number of them, along with some government officials, consider that traditional prescriptive command-and-control regulatory measures are the most effective and reliable means to achieve these objectives, despite a growing body of evidence that other forms of regulation can, if well designed, produce better results. Some parliamentarians also share this view at times. During the consultations, the NGOs repeatedly expressed a lack of faith in the ability of industry voluntary codes alone to deliver consumer protection or safety objectives, for instance. The Committee recognizes that, as is the case for all measures, there are limitations to alternative instruments, including voluntary codes. This, however, should not preclude their careful consideration and appropriate use.

The Committee believes that strengthened accountability measures are essential to fostering increased public trust. As discussed in Section 3.6.3 "New Approaches to Regulatory Action," the government should explain how the proposed instruments will help achieve the desired results. It should evaluate regulatory strategies on an ongoing basis, report on performance to the public, learn from the results and modify its approaches as needed.

3.5.2 Framing Instrument Decisions

Currently, no framework is available to assist decision makers in their policy analysis and their consideration of various instruments. The Committee recognizes that there is no one single method for creating the optimal mix of instruments. The selection of policy instruments is not a task that can be performed using a "one size fits all" tool. Each situation must be evaluated on the basis of the specific risks involved, the relevant legal framework and the needs, obligations, roles and responsibilities of all players. Yet, the Committee believes that an analytical framework could help decision makers in considering a wide variety of instruments and in finding the right match between the goals pursued and the instruments, from the initial decision to regulate or not, through to the consideration of various compliance and enforcement strategies.

Such a framework could include information on the attributes of each instrument and describe the interrelationships between them. It could also provide criteria and a series of methodological considerations to serve as a road map for decision makers in evaluating the appropriateness of instruments and their compatibility with the objectives being pursued. For instance, officials could be required to consider such matters as the level of risk to society, the industry's structure, its homogeneity or diversity, its history of conformity, the stakeholder or public pressure to resolve the issue, the government's administrative capacity, etc.

The Committee also believes that the choice of instruments should be more thoroughly debated at the outset of the policy design process. The government should cooperate with industry and citizens and build trust in the design of regulatory programs and the choice of instruments from the beginning of the policy development process. Also, to prevent decisions on instruments from being made in isolation, the government should put in place mechanisms to ensure that all relevant members of the federal regulatory community, including lawyers from departmental legal services, are involved in the design of regulatory strategies.

Finally, the Committee is of the view that departments would use a greater range of tools if the choice of instruments were more strongly challenged throughout the policy development cycle. The Committee finds that, once a decision is made to use the force of law to resolve a public policy issue, the existing mechanisms to question that decision and suggest changes should be strengthened.

This could be achieved by reinforcing the role of analysis and the challenge function of the Privy Council Office, notably by requiring that these functions be exercised earlier in the process. The new template for Memoranda to Cabinet suggests discussing "instruments available to achieve policy objectives." This is a step in the right direction in recognizing the importance of instrument consideration in policy development and implementation. Also, when it introduces a bill in Parliament, the government should provide a description of the key policy instruments to be used and a narrative of the proposed substantive regulations planned for the year following adoption of the law, as well as their intended results. These details would better inform Parliament of the full importance of the proposed legislation.

Recommendation 22: The government should develop a framework for the design and use of a mix of instruments, including compliance and enforcement strategies. It should also establish mechanisms to ensure that instrument decisions are more strongly debated throughout the policy development cycle, notably by requiring that the Privy Council Office's challenge function be exercised earlier in the process.

3.5.3 Increasing Awareness

In recent years, the federal government has provided some training and information on instrument choice to encourage officials (e.g. lawyers, policy analysts, regulatory officers) to use a wider range of instruments. Some departments have become quite successful at creating innovative mixes of instruments and working cooperatively with industry and citizens. For instance, Environment Canada's approach to pollution prevention and the protection of the environment and human health includes not only the *Canadian Environmental Protection Act, 1999*, and its regulations, but a variety of other non-legislative tools such as environmental quality guidelines, codes of practice and pollution prevention plans developed by industry.

However, the Committee notes that, despite these efforts, progress on the use of alternative instruments has been slow. This seems to be attributable to entrenched habits in the regulatory community and the result of a "vicious circle," where Canada's lack of practical experience and awareness feeds an ongoing reluctance to depart from more traditional regulatory approaches.

The federal government should pursue its efforts to help officials involved in designing, implementing and enforcing regulation to become more aware of the potential uses of alternative instruments. In the Committee's view, this should involve continued efforts to provide them with practical and focused training and information. Integrating regulatory innovation into the performance assessment of civil servants could also encourage regulators to consider innovative instruments or mixes of instruments.

Further, increasing awareness of the various instruments will require that best practices in instrument choice be given more profile and that they be shared across departments. These best practices could be supplemented by conducting a number of case studies of various alternative instruments. The results could be benchmarked against those of other countries.

Recommendation 23: The federal government should accelerate efforts to make the regulatory community aware of the various instruments available and the benefits of using a combination of tools to solve policy issues.

3.5.4 Removing Legislative Constraints

Instruments are often selected on the basis of availability. Traditional views of government and regulatory action have favoured the use of statutes and regulations as the main policy tools. Therefore, federal statutes often focus on using conventional regulations to implement the legislative schemes rather than other tools that would better serve policy objectives. This is particularly the case for older statutes, where the details of the legislative schemes are often required to be prescribed by regulations.

The problem is that when a statute requires the Governor in Council to make regulations respecting specific matters or activities, these matters or activities cannot be regulated otherwise, such as through voluntary codes or other instruments. An illustration of this principle is found in the case *Aucoin* v. *Canada (Minister of Fisheries and Oceans)*,[9] in which the Federal Court of Appeal declared illegal a partnering agreement with snow crab fishers because it was not authorized by the *Fisheries Act*. By entering into this agreement, the Minister of Fisheries and Oceans had acted beyond his legal authority.

The same problem exists with respect to performance-based regulation, a type of regulation highly favoured by larger firms — and one for which smaller firms require guidance — which sets a desired performance standard and lets the regulated community decide how best to achieve it. For instance, an environmental regulation may state the maximum level for effluent discharge, but each firm can choose the best method for restricting its discharges to meet the prescribed limit. When a statute requires the Governor in Council to prescribe the method or means for regulated parties to use in order to achieve certain results, the regulations must indicate which method is to be used. Regulatory authorities are therefore prevented from using performance-based regulations.

The *Explosives Act* and *Explosives Regulations*

The recent plain language rewrite of the *Explosives Regulations* revealed ways in which the *Explosives Act* has not kept up with the needs of the modern, greatly expanded and diversified explosives industry. Shortcomings include:

- a very prescriptive approach that does not allow an alternative means of compliance;
- no provision for the appeal of a suspension or cancellation of a licence, permit or certificate;
- no alternative enforcement mechanisms, such as monetary penalties and alternate dispute resolution — the Act is limited to the prosecution of offences;
- restrictions on the extent to which Canadian requirements can be harmonized with those in the U.S. and Europe, for example, through incorporation by reference of standards as amended from time to time; and
- an unclear relationship between the Act and the Regulations.

The Committee believes that if federal officials had more flexibility in designing regulatory strategies and if existing legislation did not limit in their options, they would consider and use alternative instruments more often.

Therefore, regulatory authorities should be asked to identify the legislative constraints they face when considering alternative instruments or performance-based regulations. These constraints should be removed through stand-alone or omnibus bills at the earliest opportunity.

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[9] 2001 F.C. (Trial Division) 800

At the same time, departments that wish to bring forward new statutes should be required to create their mix of instruments early enough in the process (e.g. prior to the drafting of the Memorandum to Cabinet) to ensure that the appropriate authorities are built into the statute and that they have the necessary tools available to them for future use.

> **Recommendation 24: Legislative constraints on creating mixes of policy instruments and using performance-based regulations should be eliminated.**

3.5.5 Increasing the Profile and Use of Economic Instruments

In addition to its broader consideration of instruments, the Committee examined the use of economic instruments to meet environmental objectives. It did so in view of Canada's ambitious environmental objectives and because Canada's experience with economic instruments is limited and lags behind that of most OECD countries, which have much greater use of such instruments to achieve environmental goals. The OECD's *Economic Survey of Canada, 2000* concluded that there was a need to increase the use of economic instruments to reinforce the polluter-pays principle.

The Committee is of the view that the Government of Canada should take a more innovative approach to regulatory governance in this area, which would involve a government-wide approach to policy development and implementation.

Economic instruments complement but do not substitute for legislative instruments. They use market-based signals to motivate desired types of decision making. They either reward desirable behaviour or penalize undesirable behaviour. They encourage the development of full cost accounting, which includes all the costs of a project (e.g. polluter-pays principle). These instruments include the allocation of property rights, fee-based measures, liability and assurance regimes and tradable permits. Applications that the government may wish to consider include a deposit-refund or rebate scheme that would encourage life cycle management of consumer recyclables, a pollution tax that penalizes those who create and emit pollutants, a restructuring of fuel excise taxes (i.e. expansion beyond transportation fuels into coal and other on- and off-road fuels), infrastructure program spending, and conditionality and tax credits as well as subsidies for renewable energy sources and technologies.

Economic instruments are a key part of the broader concept of Ecological Fiscal Reform (EFR), which involves redirecting taxation and expenditure programs to create an integrated set of incentives to achieve environmental objectives. While a number of European countries have successfully implemented various aspects of EFR over the last decade, Canada has very limited experience with it.

Economic instruments can have important advantages over other tools. Studies[10] indicate that their compliance costs can be significantly lower. Economic instruments can also reward continuous improvement and stimulate environmental and technological innovation.

International successes with economic instruments clearly demonstrate these advantages. For instance, the U.S. implemented a successful emissions trading program targeting sulphur dioxide emissions from electric utilities. Under this regime, the cap on annual emissions of sulphur dioxide acts as a performance standard, while the tradability of emissions allowances lets firms decide how they want to comply. During the first phase of the program — which took place between 1995 and 1999 — the cost to participants of reducing emissions to the target level was between 1/7 to 1/3 of the cost originally anticipated by the U.S. Environmental Protection Agency and others.

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[10] *Economic Instruments for Environmental Protection and Conservation: Lessons for Canada*, Stratos, December 2003

Several studies have estimated the annual Phase 1 cost to participants at approximately $1.2 billion, which is much lower than the original estimate of $5 billion.[11] Emissions were reduced by four million tonnes annually over this period. That number is expected to double during the second phase, which started in 2000.

Similar to other alternative instruments, the main barriers to using economic instruments in Canada appear to stem from two sources: the regulatory community's lack of awareness and experience, and, in the case of charges or taxes, resistance to what the public perceives as additional fiscal measures.

The Committee's observation is that the limited use of economic instruments and EFR means that Canada may be incurring higher costs than necessary in addressing environmental policy issues. It is the Committee's view that Canada should seriously consider economic instruments, in combination with other tools, as a means of attaining its environmental objectives. A key step could be to thoroughly examine both EFR and economic instruments. Their successful use in Canada will require collaboration across all federal departments, including Environment Canada, Natural Resources Canada and Finance Canada.

The Committee recognizes that some concerns regarding the use of economic instruments and EFR are legitimate. It is possible, for instance, that Canada's regionally diverse ecosystems, policy contexts or fiscal philosophies may make it difficult to design a "one size fits all" approach. There also appears to be a lack of detailed knowledge among decision makers, stakeholders and the public about the range of EFR and economic instruments and their operation. These factors should not preclude the examination of these instruments on a case-by-case basis.

Recommendation 25: The government should examine expanding the appropriate use of economic instruments in Canada. Efforts could include the following:

- **examining the opportunities and challenges associated with EFR in Canada and addressing whether and, if so, how EFR could be implemented to support environmental policy goals;**
- **identifying several economic instruments which could be used to attain environmental policy goals and assessing their effectiveness, either individually or as part of an instrument mix;**
- **identifying areas where fiscal measures act as disincentives to achieving environmental policy objectives and finding ways to redress the situation; and**
- **launching pilot initiatives to examine the effectiveness of economic instruments in achieving policy objectives. For example, the government could design and implement one or more pollutant charges or taxes as well as incentives to accelerate the adoption of innovative environmental technologies.** ♦

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[11] Chapter 6, *The U.S. Experience with Economic Incentives for Protecting the Environment*, U.S. Environmental Protection Agency, 2001.

3.6 The Regulatory Process

This section focuses on how regulation, in its broadest sense, is developed, implemented and evaluated. The Committee believes that the federal government needs to improve the process for making rules that affect Canadians' lives and interests. Reforming the process in accordance with the values and principles of Smart Regulation would strengthen the public trust in Canada's regulatory environment and make it an asset for citizens and business.

The regulatory process sets the basis for much of the business of modern government. Developing regulatory policy, implementing regulatory legislation, achieving public compliance with laws and assessing the effectiveness of regulatory intervention are all among the primary roles of government as it seeks to protect the public interest.

The Committee has developed recommendations that it believes reflect the interrelated nature of the regulatory system. Process improvements that focus only on part of a larger system run the risk of degrading, not enhancing, overall system performance. As in all systems, a key issue in improving the regulatory system will be balance. It is inevitable that the design and execution of the regulatory process will reflect competing objectives and interests. Timely decisions and an affordable process are valued, but so is consultation and improved analysis. More public and parliamentary involvement is desirable, but the process should avoid gridlock and delays in dealing with important public policy issues. Flexibility is another desirable attribute, but so is predictability and equitable treatment. The Committee suggests mechanisms that allow for the weighing of competing objectives to achieve a Smart Regulation process.

3.6.1 Key Challenges

The Committee heard the following key concerns related to the regulatory process:

- The coverage of the current policy is too limited: the federal Regulatory Policy is aimed only at the development and approval of regulations; a separate process exists for the development and approval of draft statutes; and quasi-legislative rules are not subject to any consistent or formal process of analysis or approval.
- In many instances, existing statutes present impediments to the application of Smart Regulation principles. One obvious example is the confusion about the application of the term "regulation" in the *Statutory Instruments Act*.
- The quality of information and analysis available to decision makers and stakeholders is variable. The current system does not provide the discipline needed to clearly express regulatory objectives and anticipated outcomes that can be measured and evaluated.
- Insufficient attention is paid to compliance and enforcement issues at the design stage of regulatory strategies. Departments are limited in their options when designing compliance strategies.
- The system is not clear or transparent for many players, who often do not understand why and how regulation is developed, when and how they may participate or obtain recourse, and how to find information about proposed or existing regulation.
- There is considerable frustration with the slowness of the regulatory process. In particular, delays in processing some regulations with minimal impact are unacceptable. There is also widespread dissatisfaction with the delays involved in processing applications for approvals, licences or other types of governmental services and with the transparency and predictability surrounding these processes.
- There is a large stock of existing regulation that is not evaluated regularly to determine if it supports the objectives of Smart Regulation. In addition, there is no evaluation of whether the regulatory process itself promotes Smart Regulation.

3.6.2 Policy and Legal Frameworks for Regulatory Action

Smart Regulatory Policy

The central government policy for regulatory intervention is the federal Regulatory Policy, the first version of which was designed in 1986 when regulation was growing at all levels. The current Regulatory Policy focuses on the development and approval of regulations (subordinate legislation). It does not apply to the development of statutes (which is governed by the Cabinet Directive on Law-making) and other phases of the life cycle of regulatory intervention such as the evaluation and removal of regulatory programs. Moreover, in the federal regulatory management system, officials who develop and assess policy options for ministerial consideration receive fragmented guidance, as guidelines are found in a variety of policy statements.

The Committee believes that a Smart Regulation approach to the regulatory management system would connect and integrate the system by bringing it under one broad policy on government use of regulatory intervention. In addition, an updated and responsive Regulatory Policy would clearly signal the political priority being placed on Smart Regulation principles and infuse the regulatory management system with new energy and direction.

The government should develop a new federal Regulatory Policy which would generally apply to all legislation, both statutes and regulations (see Annex III for a draft Government of Canada Smart Regulation Policy). Controls should be improved over specified quasi-legislation that has significant impacts on regulated parties. Furthermore, negotiating positions for treaties, conventions, international agreements and international standards that will oblige Canada to take regulatory action should be assessed in terms of Smart Regulation objectives. The Committee is aware that this would impose new requirements on the modeling of negotiating positions, but the role of international agreements in driving the form and content of regulations means that more attention must be paid to the potential consequences and impacts of negotiation stances.

Another component of the updated policy should be a new requirement to provide an explicit "public interest" rationale for a regulatory intervention. Smart Regulation's ultimate goal is to serve the Canadian public interest, and so a public interest rationale should be a key component of every major regulatory decision. A common framework that would encourage regulators to articulate the public interest considerations underpinning a decision would help in building better public comprehension of and trust in regulatory activities. A proposed model is contained in Annex II of the report.

The Committee also believes that proportionality in procedural requirements is a key element in the success of a new policy framework. Currently, the Regulatory Policy and the process requirements that flow from it apply broadly to all types of regulations (see the last page of this section for a diagram illustrating the current regulatory process). The policy and requirements do not take into account the levels of risk being addressed, the economic or social impacts of the proposals, the extent of consultation needed or the degree of controversy surrounding the proposals. In the current system, resources are not being used as "smartly" as they could. As a result, insignificant or low-impact proposals are subject to overly complex process requirements, while more significant proposals receive insufficient analysis.

A Smart Regulation approach would mean that the process requirements would be proportional to the impact of the regulation and would enable both government and stakeholders who wish to participate in regulatory decision making to focus their resources accordingly. The issue is finding the appropriate balance between the risks that regulation deals with or the impacts of regulation, and the time and resources that both government and stakeholders devote to the regulatory process. The application of the requirements under the federal Regulatory Policy should be targeted by adjusting or "tiering" requirements for analysis, consultation or pre-publication of regulatory proposals to accommodate impacts, levels of risk, degree of controversy and stakeholder need for information.

The Committee is aware that the Privy Council Office and departments already work together to ensure that the level of effort and analysis required for regulatory proposals is commensurate with their scope and impact. For instance, the *Benefit-Cost Analysis Guide for Regulatory Programs* classifies regulatory proposals according to their cost and the degree of public acceptance. Similarly, a Business Impact Test is required for "major" regulatory proposals. However, the Committee believes that tiering should apply to more procedural requirements. Further, it believes that more clearly defined "tiers" and better criteria for classification would improve the system.

It will be particularly important to streamline the process for regulations that have minimal impacts or that deal with areas of minimal risk. However, the streamlined process must remain transparent and accountable. At the same time, "significant" and "very significant" regulations must be identified and dealt with appropriately in terms of process and policy development.

Guidelines to define "less significant," "significant" and "very significant" will have to be developed, using such criteria as level of risk, projected costs for business, impact on citizens, effects on the economy, competitiveness, trade, investment, innovation, employment or sustainability, level of controversy, and degree of uncertainty about risk or risk reduction approaches. Other countries, like the United States and Korea, already use criteria such as the effects of the proposals on competition, employment, investment, productivity and innovation.

The Committee also believes that the policy importance of "very significant" regulations should be recognized and that the regulatory process for these regulations should more closely mirror that employed for statutory development. In this instance, the appropriate Cabinet policy committee approves legislative policy and drafting instructions. "Very significant" regulations are not frequent, but the Committee believes that full political involvement is appropriate for regulations that in another era may have been treated as statutes.

Recommendation 26: The Government of Canada should give priority to developing a new federal Regulatory Policy that would:

- **reflect the Committee's vision, principles and proposed regulatory strategy as outlined in this report;**
- **apply to broader aspects of regulatory intervention, including statutes, regulations, specified quasi-legislation and the negotiation of international positions; and**
- **target or "tier" the procedural requirements to accommodate such matters as level of risk and impacts.**

Smart Legislation

Legislation lies at the base of all regulatory action, but legislation itself can present impediments to the application of Smart Regulation principles. The government should identify these impediments and explore techniques to remove them to ensure that Canadian legislation is modern, flexible and effective in achieving Smart Regulation objectives.

Some of the impediments to Smart Regulation arise from difficulties in determining the scope of the *Statutory Instruments Act*. The government should introduce legislation to clarify the scope of the Act to reduce confusion and the time spent determining its ambit.

As explained in section 3.5, other existing impediments to Smart Regulation relate to the limits that departments and agencies face when they consider using alternative policy instruments or performance-based regulations. The Committee already suggested in that section that these constraints be removed through legislative amendments.

Statutes and regulations should be clearly drafted and accessible. To this end, the government should ensure that all officials involved in the preparation of legislative texts, including instructing officers, receive proper training in designing and drafting clear legislative texts and supporting documents. Improving the readability of legislation would enhance transparency, increase compliance and save time and money for those being regulated and the government.

Timelier Public Access to Legislation

The Department of Justice has initiated a three-phase project that will provide timelier public access to all statutes and regulations in both official languages. This initiative is identified as the Legislative Information Management System (LIMS) project. Phase II of the LIMS project (2003–2004) will benefit drafters, the public and stakeholders by providing:

- an authoritative online source for all regulations through an upgraded Justice Canada Web site;
- a timely and regularly updated set of regulations — regulations consolidated within a week from the date of their registration rather than on an 8-month cycle; and
- a consistent and stable link for related documentation.

The drafting of statutes and regulations should allow for modern regulatory techniques, such as the incorporation into regulations of standards developed by non-governmental bodies, international organizations or other governments, as amended by them from time to time. This technique keeps regulations up-to-date, particularly in changing areas of technical standards, and promotes interjurisdictional harmonization of regulatory standards. The government should establish a uniform policy on, and seek clear legislative authority for, incorporation by reference in regulations of standards and codes, as they are amended from time to time by external organizations or other jurisdictions.

> **Recommendation 27: Existing statutes should be reviewed to identify and remove impediments to Smart Regulation. Statutes and regulations should be clearly drafted and allow for the use of modern regulatory techniques.**

3.6.3 New Approaches to Regulatory Action

The Committee believes that the initial framework for developing regulation should be improved and that certain considerations should be injected into the early analytical and planning process. As explained below, risk-based policy analyses, performance measurement plans and compliance plans are tools to improve thinking about regulation. In this sense, they can all be seen as improving the discipline of rule making.

Risk-Based Regulation

The Committee is suggesting a significant adjustment to the analytical and briefing requirements for proposed regulatory intervention, applicable both to bills and to "significant" and "very significant" regulations, by recommending that the concept of risk management be at the basis of all proposals. Risk-based thinking would expand and complement existing analytical requirements (which are primarily based on the economic analysis of costs and benefits) to provide information that the Committee believes decision makers need. The recommended risk-based policy analysis should provide explicit and preferably quantifiable projections (with clear disclosure regarding the degree of uncertainty) of risk reduction benefits and economic consequences from proposed regulatory action, including:

- how and why risks are expected to evolve in the future (the baseline problem);
- how various instruments could be used to change the evolution of risks (instrument choice);
- how the risks would change over time as regulation is implemented (performance expectations);
- how economic impacts (especially on productivity and innovation) are likely to evolve in response to government intervention; and
- how compliance is expected to evolve as the regulatory requirements are implemented under proposed compliance strategies.

Preliminary risk-based analyses and analyses of other impacts, including compliance costs, anticipated impacts on competition dynamics, ability to invest in innovation and other dynamic effects, will form a useful basis for consultation. Second-stage analysis can be developed as more is learned through the consultation process.

The Committee recognizes that risk analysis involves judgment, not just calculation. It is also well aware that a broadly applied risk-based approach to regulatory policy development implies greater clarity and transparency about assumptions, the limits of what we understand, the uncertainty that is implicit in public policy development, and the constraints on our ability to shape the future. However, the Committee believes that providing better information on how and why risks evolve and how government action can shape the evolution of risk will not only improve transparency, communication and accountability in the management of the regulatory process. The Committee believes that it will also give decision makers the kind of information they need to make wise decisions in the public interest, decisions that will ultimately generate better regulatory outcomes and better economic performance — the hallmarks of "Smart Regulation."

Recommendation 28: The government should implement a risk-based approach to regulatory action to improve analysis and decision making by requiring that all proposals for regulatory statutes and "significant" or "very significant" regulations be accompanied by an appropriately tiered risk-based policy analysis. The risk-based policy analysis should be open for public comment and reviewed by experts in the relevant discipline.

Better Planning of Performance Measurement

Performance measurement of regulatory action is key to implementing a Smart Regulation strategy. When taking regulatory action, regulators should announce the results they wish to attain, the manner in which they intend to measure them as well as when and at what frequency they will report on them. They must demonstrate their progress in achieving these results and be prepared to modify their approach if necessary. Evidence of performance is essential to sustain public trust.

This recommendation on performance measurement is aimed at improving the initial framework for assessing regulatory performance so that the government and stakeholders will be better informed of the objectives of regulation. It is also aimed at ensuring that these objectives are measured more accurately and, equally important, that adjustments are made to legislation and regulatory programs to ensure continuous improvement. This performance measurement recommendation is closely linked to recommendation 28 concerning risk-based policy analysis and recommendation 36 dealing with the evaluation of the existing stock of regulations.

The Committee recommends that regulatory bills and "significant" and "very significant" regulations be accompanied by a public performance measurement plan that includes projected risk reduction in measurable terms, performance measures, data collection requirements, a strategy for ongoing performance monitoring and a proposed schedule for evaluation. These plans would support subsequent legislative reviews and evaluations of regulatory programs.

> **Recommendation 29: The government should strengthen the performance measurement of regulation by requiring that all proposals for regulatory bills and "significant" and "very significant" regulations be accompanied by a public performance measurement plan.**

More Attention to Compliance and Enforcement

The credibility of the law and the trust of citizens are diminished when legislation is passed that cannot be enforced. Realistic assessments must be made of the enforcement potential of new legislation and the enforcement effects on existing laws, given available resources. The current federal Regulatory Policy already requires that regulatory authorities articulate their compliance and enforcement policies when they develop regulatory proposals. However, the regulatory impact analysis statements prepared by departments with respect to regulatory proposals often lack details about compliance and enforcement strategies, and primarily the resources that will be dedicated to the program.

Implementation, compliance and enforcement need to be better considered at the outset of the policy design process to produce Smart Regulation. To this end, the Committee recommends that every proposal for "significant" and "very significant" regulations be accompanied by a compliance plan outlining the range of compliance and enforcement mechanisms, including innovative sanctions, to be used. The compliance plan should outline the resource requirements of the new regulatory program and the impact of those requirements on existing programs.

Compliance should be based on a risk management approach. Because government does not have the resources to inspect or enforce all regulations, a relationship of trust should be built whereby government compliance strategies could include incentives for businesses and citizens to voluntarily demonstrate compliance. Sanctions should also be sufficient to deter non-compliance by removing the ability to make a profit from non-compliance, for example.

Competition Bureau – Conformity Continuum

The Competition Bureau's conformity continuum is also considered an excellent example of how to maximize limited resources and leverage cooperation from partners. As part of this continuum, the Bureau has developed the following initiatives: the Fraud Prevention public awareness and education campaign, voluntary codes in association with the private sector, partnerships involving provincial and federal police enforcement agencies, cooperation agreements with foreign competition agencies, as well as participation in international organizations such as the International Competition Network.

Further, the Committee believes that compliance would be improved if officials had a broader range of possible responses to non-compliance that they could use to develop an "enforcement pyramid," moving up to more stringent responses as non-compliance becomes more severe. More legislation should include remedial sanctions, such as the alternative measures found in the *Canadian Environmental Protection Act, 1999*, or the *Species at Risk Act*.

An option would be to introduce legislation to give all departments more flexibility in creating compliance strategies and to authorize additional compliance and enforcement tools, including alternatives to regulatory prosecution, for use by all departments. Such a statute would permit all departments to take advantage of administrative innovations, enforcement alternatives and additional or alternative penalties (administrative monetary penalties, voluntary or mandatory corrective actions, suspension or revocation of licences, dispute resolution, etc.) as they evolve, whether or not these tools are expressly provided for in the statutes they administer.

Compliance and enforcement issues warrant more attention than was possible for the Committee to devote given the scope of its mandate. This is an area where the Committee suggests that the government might want to undertake more work and deeper analysis of the issues and potential areas of improvement.

> **Recommendation 30: The government should ensure that attention is paid to regulatory program implementation and compliance early in the policy development process by requiring that "significant" and "very significant" regulations be accompanied by a compliance plan.**
>
> **Recommendation 31: The Department of Justice, the Privy Council Office and federal departments should work in collaboration to introduce legislation that would make a range of compliance measures available to all departments.**

3.6.4 Transparency and Consultation

The Committee believes that transparency is a crucial element of a smart regulatory environment. Transparency must be maximized in government, as well as in industry, in order to promote learning and information sharing and to build public trust in the system's integrity. The following recommendations complement those made elsewhere in this report to increase the levels of transparency in the regulatory system.

Consultation as a Learning Dialogue

The OECD and other commentators have recognized Canada's strong performance in consulting on regulatory matters. Consultation has become part of the Canadian regulatory culture and has significantly changed the way government has done business in the last 25 years. Nonetheless, the Committee often heard cases of dissatisfaction with consultation. There was concern, for example, that consultation occurred too late in the policy development process, that government consultation efforts were not coordinated or that certain stakeholders were at a disadvantage in dealing with the demands of consultation. Another issue is that stakeholders sometimes take an adversarial approach to consultations, which is not conducive to problem solving. The government must improve its capacity to approach consultation as a dialogue, facilitating collective learning about risks, options for instruments, effective compliance strategies and the potential impacts of regulatory action.

The government should clearly frame the boundaries for consultation initiatives. This framework should include the consultation objectives, the type of comments the government wishes to receive and the timeframes and means for providing input. Such a document should provide clear rules of engagement for interested parties and help them decide whether and, if so, how to participate.

In order to facilitate citizen involvement, the Committee believes that the public should have all the information it needs during the consultation process, including the supporting rationales, the technical or scientific information, the analyses performed, the costs and benefits, the trade-offs considered, the risk assessment, the potential impacts and consequences, and the alternatives considered. The public needs to know which problems the government is paying attention to and what drives the government in solving those problems.

Yet, this information is often not shared with the public or other interested parties because it is said to be protected under Cabinet confidentiality. The Committee recognizes that Cabinet confidentiality is an essential component of Canada's system of responsible government. However, the zone of secrecy afforded to Cabinet confidences is limited to the information that forms part of the advice to a minister or the documents listed in section 69 of the *Access to Information Act*. The government should develop rigorous guiding principles on what can be disclosed in the context of consultation and what should be protected as Cabinet confidence.

One objective of public consultations on regulatory issues is to ensure that regulatory authorities are aware of a broad spectrum of perspectives and ideas. In this regard, consumer organizations are under-represented in consultative processes and do not have the resources to undertake the research and develop the expertise required to contribute to consultations on regulatory issues. Their capacity for constructive dialogue should be fostered by selective funding, for example. To ensure that the provision of participant funding does not distort the level of interest in a proposal by creating a financial incentive for intervention, the allocation of funding should be conditional on the provision of good quality research and analysis. The criteria for eligibility and the maximum funding available should be clearly communicated. A short-term solution could involve increasing the funds allocated to the Industry Canada Contribution Program for Consumer and Voluntary Organizations, which totalled only $1.69 million in 2003–2004. Additional funding allocated to this program could be directed to projects involving regulatory issues with significant impacts on consumers.

An interesting model of participant funding is provided by the Canadian Radio-television and Telecommunications Commission (CRTC), where the Commission has the authority to reimburse some or all expenses incurred by an intervener in a telecommunications proceeding. At its discretion, the CRTC may award such costs when it deems that they were incurred by an intervener who represents a group of consumers that has an interest in the outcome of the proceeding, has participated in a responsible way and has contributed to a better understanding of the issues. There is no fund established for this purpose. Rather, the telecommunications firms involved in the proceeding reimburse the interveners. The CRTC determines the extent of costs that are to be awarded, the telecommunications firms which will be required to pay and the amount (or the percentage) which they will each be required to contribute.

As citizens' expectations to be heard and take part in the policy process continue, the government will need to explore new consultation techniques and find creative ways to provide for increased and more meaningful citizen involvement. The Committee recognizes that this is a difficult and challenging task, one with which all governments of pluralistic societies struggle. It is a key issue of modern policy development that the government will have to address. This is an area where it will be necessary to experiment and learn. It would be useful to monitor experiences in other organizations (e.g. Canadian Policy Research Networks), other jurisdictions (e.g. the Government of Ontario) and other countries.

> **Recommendation 32: The government should improve its capacity to approach consultation as a dialogue that promotes collective learning about risks, options for instruments, effective compliance strategies and the potential impacts of regulatory action. It can do this by improving coordination, increasing financial support to consumer groups, exploring new consultation techniques or mechanisms, and developing and disseminating guiding principles to more clearly frame consultation exercises.**

Harnessing the Potential of E-Government

The Committee believes that e-government would provide a powerful Smart Regulation tool for citizen engagement by offering opportunities for communication, consultation and collaboration as well as single window access to government regulatory programs. Such an approach could eventually go beyond the federal government and include provincial and territorial governments. The Committee recommends that the government establish a Smart Regulation Internet gateway that would allow the public to more easily and reliably access information about regulation by sector, subject matter or department. The gateway should provide information on current consultations and links to relevant departmental Web sites. It could be used as a tool to foster coordinated consultations by different departments on various regulatory proposals affecting specific sectors or groups.

Departmental Web sites should provide information about regulatory programs, compliance policies, impact analyses and background documents to analyses. In addition, each department and agency should publish on its Web site an annual virtual regulatory agenda that would provide information on such matters as advance notice of intention to develop regulatory proposals, consultation processes and schedules, legislative reviews, evaluation plans and performance measurement plans. The agenda should also include project plans and timetables for both legislative development and the development of "very significant" and "significant" regulations.

> **Recommendation 33: The government should capitalize on the potential of e-government as a tool for citizen engagement and as a vehicle for single window access to government regulatory programs; in particular, a Smart Regulation gateway and departmental virtual regulatory agenda should be established and maintained.**

3.6.5 Timeliness and Efficiency

Timeliness and efficiency are key principles of Smart Regulation. Regulators must strive to ensure that both the development of regulations, as well as the delivery of regulatory programs better reflect the pace at which business operates and new knowledge develops.

Throughout its mandate, the Committee heard many complaints concerning unreasonable and unexplained delays in decision making by regulators. The Committee fully recognizes that, in the current fast-paced environment, the regulator is faced with making difficult decisions with imperfect, sometimes conflicting information. In these circumstances, it is in the public interest to take the time to conduct a more thorough analysis.

In order to maintain credibility and trust in the regulatory system, regulators must be transparent. The reasons for the delay should be explained to make it clear as to why a decision calls for more time. This would help ensure that the lack of timeliness is not linked to poor program management or lack of service standards, but rather to a legitimate complexity that regulators must manage in order to make the best decision.

Timelier Development of Regulations

There is widespread agreement that the regulatory process is in need of streamlining. Streamlining is closely tied with recommendation 26 dealing with targeting or "tiering" the requirements of the federal Regulatory Policy.

As explained earlier, one way to streamline the process is to decrease the procedural requirements for "less significant" regulations. Another method is to transfer the authority to make administrative and selected "less significant" regulations from the Governor in Council to the responsible Minister. Transferring such authorities would give departments and ministers more flexibility in carrying out their activities and would relieve the regulatory process from dealing with matters that should be dealt with administratively. However, transparency and accountability must be maintained in accordance with the principles of Smart Regulation.

Timelines for a Single Jurisdiction for Disinfectants and Sanitizers

The timing for decisions regarding applications for approval or for modifying or introducing a regulation is most often at the sole discretion of the regulators. This situation can be a particular problem for low-priority issues where resource limitations preclude action and there is no defined timeline for response.

For example, 10 years ago, as a result of the need for "more efficient regulations" expressed in a Speech from the Throne, Health Canada identified the need to amalgamate the administrative window for submissions of disinfectants and sanitizers. There were two sets of regulations and, as of 1997, two sets of maintenance fees for the same product because it might be used for different purposes. The intended amalgamation would stop duplication, and save time and money for both government and industry. While Health Canada has made some efforts to streamline the regulatory process in recent years, the objective of amalgamating the two sets of regulations has not yet been achieved. Industry is still waiting for the regulatory change to consolidate responsibility under therapeutic products and make the regulations more efficient.

To further streamline the regulatory development process, the government should explore broader exemptions from pre-publication in the *Canada Gazette*, Part I, notably when established standards for consultation are met. These standards will have to be developed, but may relate to such matters as the ability to identify and involve stakeholders, ongoing stakeholder participation in regulation through advisory groups and established consultation mechanisms, and the adequacy and accessibility of information. However, where there are legal requirements for pre-publication in domestic legislation or in international agreements, regulations made under these statutes or agreements should continue to be pre-published.

Government may also wish to explore streamlining the pre-publication process by providing for ministerial authorization of pre-publication in the *Canada Gazette*, Part I, and eliminating the need for Cabinet authorization for pre-publication at this stage.

Project planning and project management discipline should be applied routinely for "significant" and "very significant" regulatory initiatives. The Committee believes that identifying targets, setting schedules for action and developing performance standards for selected parts of the regulatory management process, such as intradepartmental approvals, would improve the timeliness of regulatory development, enhance service to the public, increase the transparency of governance functions, and foster a constructive approach to accountability for regulatory performance.

Potential for Streamlining

The Canada Revenue Agency has identified potential areas for streamlining by empowering its Minister to make decisions on routine or repetitive regulations that are narrow in scope or significance. For example, regulations under the *Excise Act* listing brands of cigarettes or other tobacco products that are exempt from special export duty could be updated quickly if amendment authority were vested in the Minister. Similarly, timely additions and deletions to the listing of foreign universities that are eligible to issue tax receipts under the *Income Tax Regulations* could be handled by ministerial authority.

Recommendation 34: The government should develop new approaches to allow for more timely development and approval of regulations, including exploring broader exemptions from pre-publication requirements, improving project planning discipline and developing performance standards for appropriate stages of the regulatory process.

Timelier and More Efficient Delivery of Regulatory Programs

The Committee believes that when designing and implementing regulations and regulatory programs, serious attention should be paid to the concerns of regulated parties about efficient, timely and predictable service.

The Committee heard of cases where firms seeking governmental approval for a product were dissatisfied with the delays involved in the processing of their application and the lack of transparency and predictability around the approval process. One such example involved a small company that waited for more than a year for a federal department to process an application for approval for a new product that had been approved in the United States in only three months. Some of the reasons given for the delay were workload and other priorities, but the only recourse for the company was to write to the Minister and to ask for the assistance of the Member of Parliament. The Committee is concerned that such delays in the provision of government services can prevent consumers from having access to innovative products and cause significant economic losses to businesses, possibly jeopardizing their position in the marketplace in certain cases.

Industry Canada's BizPal: Service for Small Business

Compliance with regulation imposes a cost on businesses in their day-to-day operations. Small businesses are disproportionately affected as they are less likely to have the financial and human resources and the expertise to deal with regulatory requirements.

To help small businesses become more productive and competitive, Industry Canada has initiated a multi-jurisdictional partnership to provide online services for business licences and permits. BizPal acts as a single window to identify the licences and permits businesses need to operate at the municipal, provincial/territorial and federal levels. It represents a flexible, time-saving and practical approach to facilitating regulatory compliance for small business. The initiative also contributes to the efficiency of the licensing process by allowing for substantial savings for both business and government through the use of technology, and by providing a vehicle to identify and eliminate overlap and duplication in licensing requirements across jurisdictions and departments.

One response to cases like this would be to ask departments and approval agencies to develop service standards for regulatory programs, particularly when they involve approvals, licensing, permits or other types of regulatory responses.

By passing *An Act Respecting User Fees* (C-212), Parliament recently recognized the importance of establishing service standards in maintaining good services, particularly in the context where user fees are being charged for those services. This bill puts in place legal requirements that regulatory authorities must follow when setting or amending user fees for services. One of these requirements is that regulatory authorities establish standards for the services for which fees are being charged "which must be comparable to those established by Canada's major trading partners and against which the performance of the regulatory authorities can be measured."

The Committee supports the idea of establishing service standards and believes that they should be broadly applied. This principle is strongly supported by many industry stakeholders for whom a key concern is that, too frequently, either there are no clear deadlines under regulatory assessment processes, or they are not consistently respected by all parties. Among other issues, the Committee heard that deadlines were not always respected by all parties involved in environmental assessment processes under the *Canadian Environmental Assessment Act.*

The government could also explore other techniques to ensure that the regulated party receives timely service. For example, reversing the onus so that an application is deemed approved and the product may be marketed unless the government responds within a certain time, or requiring reasoned explanations if statutory service targets are not met, would ensure that timely service remains at the forefront of government considerations. As an example, this is essentially the way the new substance notification process works under the *Canadian Environmental Protection Act, 1999.*

As suggested earlier in recommendation 33, the government should use e-government to offer single window access to the various regulatory programs. This would help improve and coordinate the delivery of government services.

> **Recommendation 35: The government should improve efficiency, timeliness and predictability, and enhance transparency in the provision of government services. This should include the development of service standards and the use of e-government as a vehicle for single window access to government regulatory programs.**

3.6.6 Accountability, Performance and Oversight

Accountability and evidence of performance are essential to sustain public trust. The Committee already suggested in recommendation 29 that the government strengthen the performance measurement of regulation by ensuring that "significant" and "very significant" regulations and regulatory bills are accompanied by a public performance measurement plan. That recommendation would apply only to new regulatory proposals. The recommendations below deal with the performance review of existing regulation, the performance monitoring of the regulatory process, and the monitoring of the implementation of the Smart Regulation strategy.

Review of Existing Regulation

The Committee believes that the government must give higher priority to updating and modernizing existing regulation. More attention must be paid to ensuring that the large stock of regulation does not impede Canada's ability to be an innovative and competitive country with modern regulation that is protective, up-to-date, flexible and responsive. A smart regulatory system should be self-renewing, continuously improving and include a built-in learning approach.

For example, each department or agency could prepare and publish an annual regulatory evaluation plan that would set out the evaluations to be completed in the coming years. Each plan would need to link to any available performance measurement plans for the program or legislation being evaluated. Priority for evaluation should be given to areas of higher risk, areas of rapidly changing science or technology, or areas where substantial degrees of uncertainty existed at the time the program or legislation was developed, for example where the precautionary principle was relied upon. The public could also be asked to suggest areas of regulation for priority review.

Another option would be to create multistakeholder "swat teams" around an industry sector or an area of regulation. These swat teams could include representatives from industry, provincial and territorial governments, Aboriginal organizations, non-governmental organizations and others. They would be asked, within a set timeframe, to identify the regulatory issues to be addressed and to propose means to resolve them.

> **Recommendation 36: The government should establish an ongoing program of evaluation and modernization of existing regulation, based on the priorities set out above, to ensure that regulation evolves with social needs and scientific advances. A mechanism by which the public can suggest areas of regulation for priority review should be established.**

Monitoring Performance of the Regulatory Process

Finally, the Committee believes that continuous attention to the performance of the regulatory process will be an essential element in ensuring success for the Smart Regulation strategy.

The government needs to evaluate how well its regulatory management system is operating so that it can determine whether the quality is improving over time and whether mid-course corrections are needed. The government should establish performance criteria and indicators in order to monitor, evaluate, report on and adjust the process to ensure that it is effective at fostering the principles and objectives of Smart Regulation.

> **Recommendation 37: The government should establish performance criteria and measures for the regulatory process to ensure the principles and objectives of Smart Regulation are being fostered.**

A) PCO Challenge Function

During the consultations, both external stakeholders and government departments emphasized the need for more thorough and consistent enforcement of the Regulatory Policy and more leadership from central agencies on regulatory matters. The Committee believes that the Privy Council Office must strengthen its challenge function. This will be particularly important if a new Regulatory Policy is adopted by the government. PCO's leadership will be critical in advancing Smart Regulation throughout government.

It is PCO's role to ensure that departments comply with the Regulatory Policy. The main point at which it exercises its challenge function is at the end of the policy development process when a new regulation is developed. It is important for PCO and other central agencies such as the Treasury Board to exercise the challenge function and management oversight throughout the policy cycle, from development to implementation and enforcement.

As guardian of the policy, it is also PCO's responsibility to monitor its relevance and ensure continuous reform. It should therefore play a lead role in the development and implementation of policy research and policy development agendas (see Section 3.7 "Government Capacity"). Recently, work has been done in the areas of consultation and performance measurement. Other areas could include the tiering of the submission process, risk-based policy analysis and compliance plans.

Finally, PCO should become a centre of expertise on regulation and provide advice and support to departments with respect to the implementation of smart regulatory practices. PCO should work with regulatory authorities to develop a government-wide regulatory agenda and advance it in support of government priorities. The implementation of these proposals would require the allocation of further resources to PCO.

B) Departmental Recourse Mechanisms

One way to increase transparency and trust in the regulatory system is to enhance stakeholders' access to government and provide mechanisms to permit them to challenge departmental decisions.

Currently, very few programs enable stakeholders or citizens to challenge a department's decision or offer a process for resolving disputes. For example, when a company disagrees with a department's position, when a complaint remains unanswered or when there is a delay in the development of a new regulation, the regulatory department is the only point of access for stakeholders. Stakeholders' main course of action is to bring the issue to the attention of senior governmental officials, in the hope that they will be more responsive, or to ask for help from their Member of Parliament. This situation raises issues of lack of transparency, which can result in a lack of trust in the regulatory system.

Most of the time, the only recourse is the court system, which is appropriate for legal issues but is a long and costly process when the use of a mediator could sometimes suffice in resolving an issue. The courts are not necessarily the most appropriate or efficient means to resolve policy issues, lack of service standards or deficient management practices.

The Committee is of the view that contestability within the regulatory system needs to be increased and that appropriate recourse mechanisms should be put in place. This point was expressed frequently by a wide range of stakeholders during the Committee's consultations. Better mechanisms for recourse are also recommended in a recent report by the George Morris Centre entitled *The Competitiveness Impacts of Canada's Agricultural Products Approval Regulations*.

The following are different options for increasing contestability within the regulatory system and access to government for stakeholders and citizens. They can be established as stand-alone initiatives or used in combination, and their use can vary over the life cycle of regulatory reform.

An independent third party in the form of an expert panel could provide a review mechanism when the contentious issues are technical, scientific or economic in nature. This panel could receive submissions from the regulator and the stakeholder. This approach is generally voluntary and the recommendations of such a panel are not necessarily binding, depending on the nature of the issues. An example of such a mechanism can be found in the *Act Respecting User Fees* (C-212), recently approved by Parliament. The Act requires each regulating authority that sets user fees to establish an independent advisory panel to address client complaints about the user fees. The implementation of this measure should be monitored in order to draw relevant lessons, which could be applied to other regulatory issues.

Another option could be the appointment of a regulatory ombudsman — either within individual departments or for the government as a whole. Ombudsmen usually have investigative and recommendation-making power.

During the consultations, many stakeholders suggested that the recourse function be held by PCO. The Committee recognizes that this would be a new role for a central agency which could be at odds with its traditional challenge function.

The Committee believes that different models should be assessed. This may be an area where the government would want to test an approach for one year before institutionalizing such a function. The authority given to such a mechanism could include mediation, investigation, information collection, and the ability to convene public hearings and make recommendations. Transparency and fair access should guide its operation.

> **Recommendation 38: The federal government should establish a recourse mechanism independent of the regulatory program to provide an opportunity to stakeholders and citizens to challenge regulatory performance and decisions.**

C) External Oversight Mechanisms

Some stakeholders have suggested the establishment of a permanent external advisory committee such as the United Kingdom's Better Regulation Taskforce. In the Committee's view, the creation of multistakeholder "swat teams" — a collaborative approach involving diverse stakeholders with experience and knowledge in a given economic sector — would be more effective in the short term to maintain the momentum on Smart Regulation (see Part III, "Making it Happen"). It believes that it may be more effective to convene another external advisory committee in two years to assess the progress made by government towards Smart Regulation.

The Committee notes that parliamentary committees are currently involved in the review of legislation, primarily statutes and some subordinate legislation. In recent years, they have expressed increased interest in regulation. Many stakeholders have suggested that parliamentary committees could assist and be involved in reviews of specific regulatory programs. The government may want to give consideration to this idea.

The Committee also notes that the *Canadian Food Inspection Agency Act* requires the appointment of an independent advisory board to advise the Minister of Agriculture and Agri-Food, which represents a form of oversight of the Agency. A board was appointed for a three-year term in 1998 but has been neither renewed nor replaced since its dissolution.

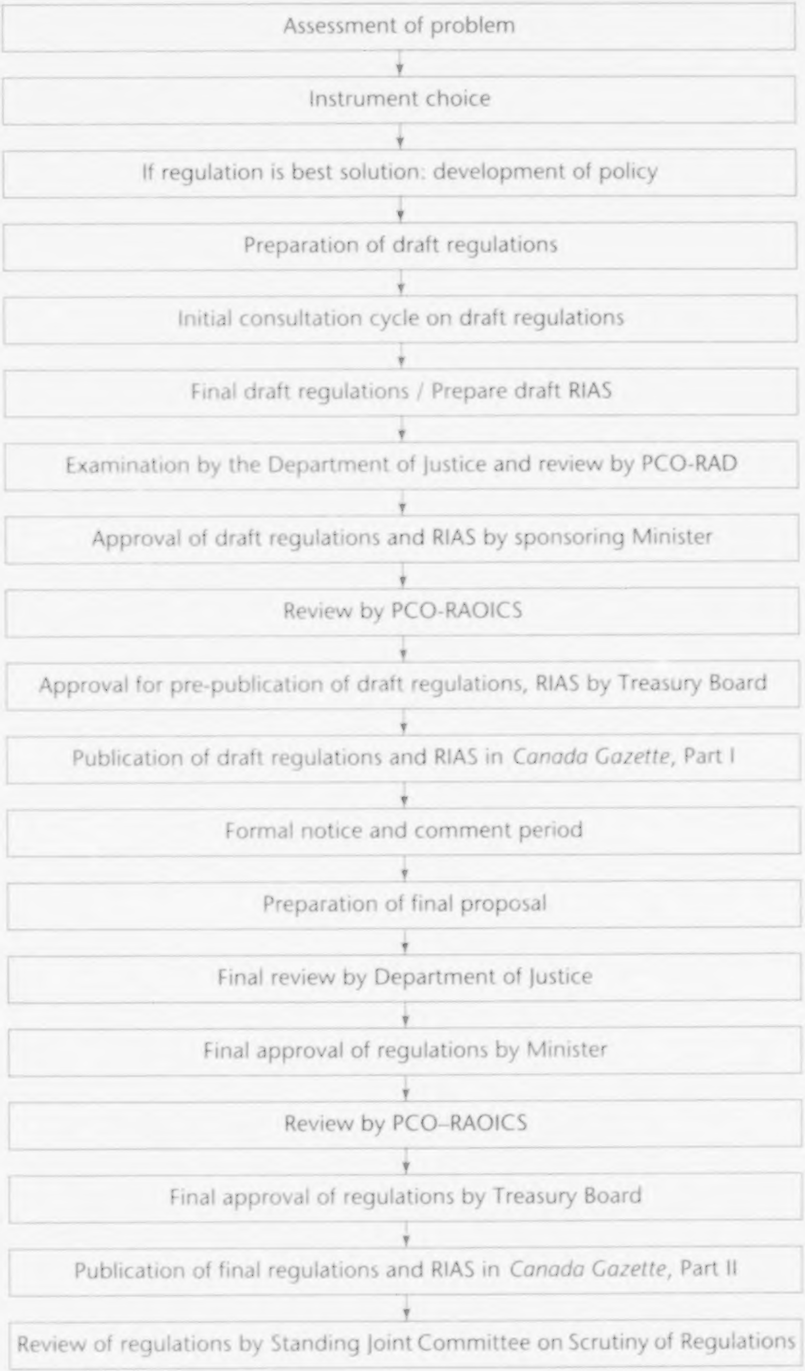
> **Recommendation 39: Another external advisory committee should be convened in the medium term (e.g. two years) to assess the government's progress in transforming the regulatory system.**

3.6.7 Implementation of a Smart Regulatory System

Some of the recommendations in this section can be implemented relatively quickly and without significant diversion of resources. Other recommendations, however, represent a profound change in how government develops, decides on and implements regulation, and how it evaluates and modernizes existing regulation. For example, a risk-based approach to regulatory action will shift the emphasis of the analysis of the regulation's potential effects. Similarly, effective tiering will require officials to determine the appropriate tier and the consequent process for proposed regulations. Additional work will be required to develop the policies, guidelines, performance standards and implementation guides necessary to put many recommendations into place. The first step in making Smart Regulation a reality will be to develop a strategy and implementation plan, with its own milestones, for reforming the regulatory process. The Committee urges the government to be both realistic and transparent in its approach to implementing process reforms for the Smart Regulation initiative.

The Committee knows that officials and stakeholders do not have unlimited capacity to respond to increased demands. This fact needs to be recognized and ways found to make smarter use of existing capacity. In addition, it is important that new requirements, such as the analysis of more significant regulatory action, be balanced with streamlining and reducing the internal burden in other areas. Just as regulation itself is often a balancing of competing interests, so too must the design of the regulatory process reflect competing objectives and interests, such as timeliness versus improved collaboration, information and analysis. The Committee knows that finding this balance is not always easy, but believes that it will be vital to creating a process that produces the Smart Regulation that Canada needs.

CURRENT REGULATORY PROCESS


Assessment of problem
Instrument choice
If regulation is best solution: development of policy
Preparation of draft regulations
Initial consultation cycle on draft regulations
Final draft regulations / Prepare draft RIAS
Examination by the Department of Justice and review by PCO-RAD
Approval of draft regulations and RIAS by sponsoring Minister
Review by PCO-RAOICS
Approval for pre-publication of draft regulations, RIAS by Treasury Board
Publication of draft regulations and RIAS in Canada Gazette, Part I
Formal notice and comment period
Preparation of final proposal
Final review by Department of Justice
Final approval of regulations by Minister
Review by PCO–RAOICS
Final approval of regulations by Treasury Board
Publication of final regulations and RIAS in Canada Gazette, Part II
Review of regulations by Standing Joint Committee on Scrutiny of Regulations

LEGEND: PCO-RAD: Privy Council Office – Regulatory Affairs Division
PCO-RAOICS: Privy Council Office – Regulatory Affairs and Orders in Council Secretariat
RIAS: Regulatory Impact Assessment Statement

3.7 Government Capacity

The changes recommended by the Committee represent a call for a cultural change within government in general and within regulatory departments in particular. Public service officials often expressed the need to provide increased support to the regulatory community. This message was heard just as frequently from industry and non-governmental representatives who are in regular contact with regulatory officers and have a good appreciation of their reality. The Committee realizes that building departmental capacity is one of the keys to improving regulatory performance.

Regulatory officials face tougher and more complex problems than ever before. In biotechnology, for example, which combines issues in the fields of ethics, economic restructuring and science, regulatory officers must grapple with difficult intellectual issues and with the philosophical foundations of regulatory decision making in a pluralistic democracy. They are required to have both a specialized understanding of the sector (from the science behind it to the issues in the boardroom) and the broader socio-economic perspectives required for good public decision making.

The Committee is proposing extensive changes to the regulatory system. Priorities will have to be adjusted, resources assigned to different tasks, new skills developed, existing competencies enhanced, best practices and expertise shared, and new systems developed. These changes will probably take many years to achieve. Transforming how government regulates will also take commitment, leadership, resources, time and support, and an underlying recognition of the importance of regulation to Canadian society. This subject is addressed in more detail in Part III, "Making It Happen."

This section focuses on government capacity. However, the Committee recognizes that a Smart Regulation system will also involve building capacity in the private sector and among NGOs and Aboriginal communities.

3.7.1 Developing a Leading-Edge Regulatory Community and Supporting Learning

As in any knowledge enterprise, human resources are the most important asset. The regulatory system is no different. Stakeholders, particularly industry representatives, often told the Committee how important the quality and competency of the regulatory staff is to the effectiveness of the regulatory system.

Several human resource issues were raised with the Committee. There is a decline in the public service's knowledge and understanding of industry sectors (structure, consumer trends, criteria for investment decisions and technological developments). It is difficult to attract and retain expertise, particularly in the fields of science and technology. The Committee was often told, again by external stakeholders, that regulatory jobs in the public service warrant more prestige and that there should be more learning opportunities offered to the regulatory community. Lastly, regulatory officers who have consumer protection or health and safety mandates feel a value conflict if they are asked to work more closely with the regulated parties or to be sensitive to economic growth.

The Committee recognizes that public servants working in regulatory programs have an important responsibility. Their decisions can have a direct impact on the health and safety of people and the environment, and on the competitiveness of an industry sector or the viability of a firm. They have to deal with increasingly complex issues and high expectations. Departments used to be able to rely mainly on the expertise of specialist groups to regulate particular activities (e.g. veterinarians making animal health decisions, and engineers setting automobile safety standards). Now these people must not only be at the leading edge of their own increasingly specialized domains and participate in and have access to international expert networks, but they must also have significant skills in fields beyond their traditional areas of expertise. Officials are now required to understand the rules of international trade and operationalize concepts like sustainable development. They must also manage consultations and negotiations with much broader, more sophisticated stakeholder communities.

The Committee's proposed vision and recommendations call for new roles for regulators in the 21st century. The regulatory community will need to develop new competencies in response. The Committee believes that learning is a powerful tool for change and must be an integral part of a Smart Regulation strategy. It supports the objective of the *Policy for Continuous Learning in the Public Service of Canada,* which states that the public service must become a learning organization "to fulfill its mission as a national institution in the knowledge age, [and] to maintain the trust of those it serves." The Committee is of the view that the federal government should apply this approach to regulators and promote the development of a government-wide learning community.

Efforts to this effect have already started. Over the last two years, the Privy Council Office has organized learning events that were very well attended, demonstrating that regulatory officers have a need and an appetite for learning. The Department of Justice has also launched learning initiatives on instruments. The Committee applauds these initiatives and believes that strengthening them will support the implementation of Smart Regulation throughout government.

The Privy Council Office has started to identify the key elements of a strategy to support the development of a leading-edge professional regulatory community across government and to foster a culture of continuous learning. The government must pursue this work and develop a learning strategy. This strategy could include the sharing of best practices, mobility across departments, orientation courses and a system to disseminate knowledge across regulatory departments and agencies. Provincial and territorial governments should also be considered in capacity-building initiatives as well as Aboriginal communities and stakeholders, as appropriate. Many provinces and territories have expressed an interest in working with the federal government to identify and address training needs and help maximize the use of scarce resources.

At the same time, the federal government needs access to the latest and best scientific research to guide its regulatory decision making. However, given the rapid pace of scientific discovery and the increasing specialization of certain research fields, it will become increasingly difficult to maintain a critical mass of scientific capacity within the federal government. The Committee has noted that Canada has made significant investments in support of research networks across the country (e.g. the Networks of Centres of Excellence program) and feels that the government should take advantage of these national networks in regulatory programs — in addition to existing international networks — to supplement their in-house scientific knowledge. By tapping into these existing resources, Canada will be in a better position to inform its regulatory decision making with cutting-edge science and conduct scientific peer reviews when needed.

3.7.2 Developing Policy Capacity

Throughout this document, the Committee has stressed the cross-governmental nature of many regulatory issues and the need for greater and more effective coordination. While regulation is an important tool for government action, the federal government has no policy research and development agendas in this area. The Committee believes that to support continuous improvement in the regulatory system, which is at the heart of Smart Regulation, ongoing policy research and development agendas are needed. These agendas would stimulate new thinking and innovation in the regulatory domain.

The Regulatory Affairs Division in the Privy Council Office, which is the guardian of the regulatory policy, could take the lead. It could work with federal departments and strike the appropriate partnerships with organizations and individuals from outside the public service to build a national regulatory capacity.

On the policy research side, the lack of research on governance in general is already recognized, as indicated in the *Preliminary Governance Research Plan* produced by the former Canadian Centre for Management Development (CCMD) in March 2003. In addition, there is a relative paucity of academic work on what Malcolm Sparrow calls the "regulatory craft." The Institute for Public Administration in Canada has already expressed interest in being further involved in research into regulation. Other partners could include the research group at the Canada School for Public Service, the Policy Research Initiative and academics. In addition to developing a policy research program, research chairs in regulatory areas could be funded through the Social Science and Humanities Research Council. Partnerships between government and universities could benefit both sides, with graduate students participating in government regulatory programs and regulatory practitioners serving as adjunct professors.

Risk management and international regulatory cooperation would be two priority areas of a policy development plan, as suggested earlier in this document. The plan could also include the development of common methodologies and tools for regulators. It would be worthwhile to seek input from the provincial and territorial governments, the private sector and non-governmental organizations and to establish links with international organizations such as the OECD on such a plan.

Partnering with these institutions would help to develop a regulatory community of practice, create synergies and support the implementation of a national vision for regulation.

3.7.3 Providing High-Level Leadership

This section contains a number of recommendations, but the Committee believes that political commitment is a precondition to successfully creating and managing an effective Smart Regulation system. Political decision makers must send out a consistent message that they value a Smart Regulation process, and government and parliamentarians must encourage a Smart Regulation ethic and culture.

Change will require sustained leadership and commitment at the senior levels of the public service. Senior officials in the Privy Council Office will have to drive this agenda in order to support change at a general level and encourage innovators and change agents in the system to come forward with new ideas and concepts.

Deputy ministers will also have an important role to play in setting the direction, providing guidance and ensuring the progress of the smart regulatory agenda. Through a committee such as the Deputy Minister Group on Smart Regulation, they could coordinate and advance regulatory initiatives and maintain the momentum for change and continuous improvement. They could also champion initiatives such as developing and raising the profile of the regulatory community.

3.7.4 Enhancing Information Gathering and Analysis

It is recognized that the public service needs better systems to generate the information that supports decision making. This is also true in the regulatory area. The Committee sees the need to improve systems that support regulatory decision making. There was little data readily available on regulatory programs when the Committee was in the research phase of its work. For example, the Committee has not been able to establish how much the federal government spends on regulatory programs or how many persons work in this area. There is also very little data on how regulatory programs help the government achieve its policy objectives. Internationally, there is no inventory of cooperation initiatives or systematic monitoring and compilation of regulatory developments in key countries. The Committee is not recommending launching a costly and bureaucratic exercise. But it feels that government needs to improve its ability to collect and disseminate regulatory data and to analyze and use this kind of information. That is how it will continuously learn and improve its practices.

For more discussion on performance measurement, see Section 3.6 "The Regulatory Process."

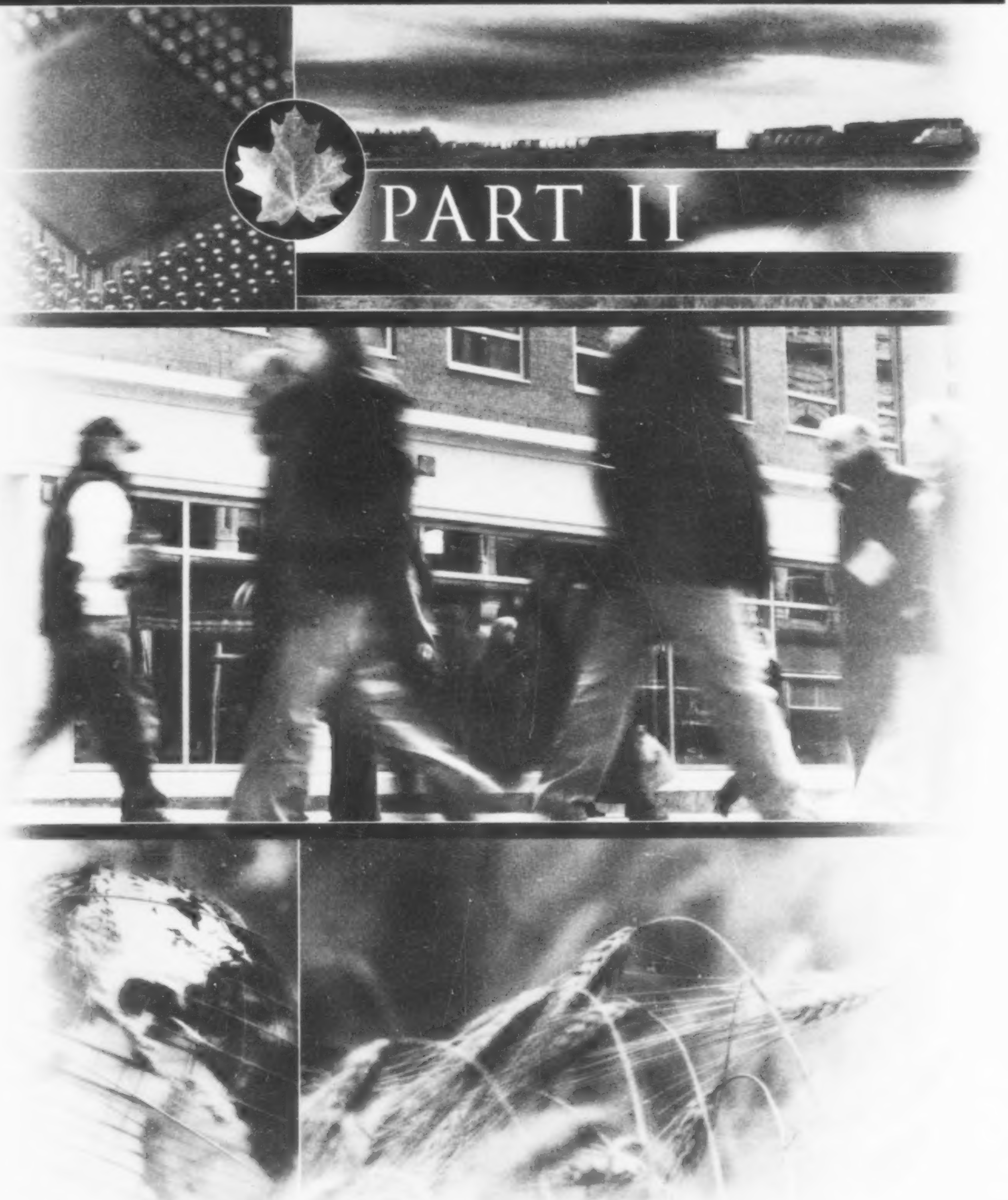
3.7.5 Resourcing

Many officials have stressed the need for additional financial resources, particularly to implement the Committee's recommendations. Others have said that the lack of new funding should not be an excuse for failing to work within existing budgets, including reallocating resources.

While the Committee has not quantified the cost impact of its proposals, it has tried to be sensitive to these costs. However, while some initiatives may be accomplished by reallocating resources, the Committee thinks that the transition to a new way of conducting regulation in the 21st century could benefit from, and be accelerated by, some additional resources.

> **Recommendation 40: The government must develop and implement a comprehensive learning strategy for the regulatory community.**
>
> **Recommendation 41: The government should develop and implement regulatory policy research and development agendas in collaboration with appropriate partners from outside the public service.** ✱

PART II



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SECTORS/AREAS OF REGULATION

Introduction

As the second and third elements of its mandate, the Committee was asked to identify sectors and areas of regulation requiring regulatory reform in Canada. The Committee was also asked to consider areas that could be at risk if regulatory frameworks were not examined and possibly reformed. Its objective was to identify key industry sectors, stewardship regimes and regulatory programs in which regulatory reform would give Canada a strategic advantage and support our country's social, environmental and economic goals. Building on the analysis and recommendations outlined in the strategy in Part I of the report, Part II demonstrates how Smart Regulation can be applied to specific case studies.

The Committee used five criteria to select priority sectors or areas for analysis:

1. The sector or area offers economic opportunity and social/environmental benefits for Canadians.
2. There is pressure for change from industry, the Canadian public, government or international sources.
3. The sector or area demonstrates the enabling and protecting attributes of Smart Regulation.
4. The regulatory framework is a strategic asset for industry and for Canada.
5. There is potential momentum for a Smart Regulation strategy.

In addition to these criteria, the Committee undertook a scan of regulatory issues and took into account the concerns and issues raised by regulators and stakeholders across the country. The Committee also wanted to examine issues which were cross-cutting in terms of having a wide impact on Canadian society and the economy. Based on these considerations, the Committee examined the following subjects: manufacturing and product approval; biotechnology/life sciences; First Nations economic development; the environmental assessment process; and oil and gas exploration and development.

The Committee recognizes that these issues are not the only regulatory priorities facing the Government of Canada and feels strongly that all sectors or regulatory areas should be subject to ongoing evaluation and modernization, as recommended in Part I of the report, in order to reflect the principles of Smart Regulation. The review did not focus on the merits of the policy objectives for these areas of regulation. Instead, the Committee sought to identify how Smart Regulation could be applied to existing Canadian regulation in order to better advance economic, social and environmental policy objectives. In developing its recommendations, the Committee endeavoured to ensure that they reflected the vision and principles discussed at the beginning of the strategy: cooperation, effectiveness, cost-efficiency, timeliness, transparency, accountability and performance.

In undertaking this analysis, the Committee made the following overall broad observations:

> ***Coordinating regulatory action*** – The federal government should better coordinate regulatory intervention between federal departments and agencies and with other orders of government. At the outset, the federal government should ensure that its regulatory functions are coherently aligned with its policy priorities. Specific initiatives should be implemented, such as the provision of single window service and the designation of federal coordinators with appropriate authority to oversee federal regulatory involvement in major projects. This is particularly critical in the cases of environmental assessment, biotechnology/life sciences, and the oil and gas exploration and development sector.

Developing regulatory policy frameworks – *The Committee found an occasional gap* between the objectives of a regulation and its actual impact, particularly when more than one department was involved. Accordingly, there is a need to establish overarching regulatory policy frameworks that clearly and concisely spell out the government's objectives in a sector or area of regulation. These frameworks would provide overall guidance to the various regulatory authorities, identify success criteria and ensure the regulatory action is coherent and integrated. The Committee found that the need to establish such frameworks was particularly evident in the automotive, biotechnology/life sciences, and offshore oil and gas industries.

Creating timely and responsive regulations – The Committee found that the current regulatory environment does not adequately adapt to external changes such as those found in business, technology or consumer choice. Regulations must be flexible enough to address advances in production methods and service delivery in a timely manner. One of the remaining challenges is that many federal regulations are prescriptive, rather than based on performance and results. The greater use of performance-based regulatory standards would give stakeholders the flexibility to comply with these standards through innovative means while still respecting the policy goals of the regulation.

Understanding cumulative and unanticipated impacts of regulation – The government needs to become more aware of the cumulative impacts of existing and proposed regulation. This understanding would be a first step in developing a greater sensitivity to the constraints that are inadvertently created by regulation and how an "enabling" dimension can be added to regulation. This observation applies to all sectors.

Maximizing transparency and consultation – The Committee found that many existing regulations continue to be difficult to understand and that many stakeholders do not know how to participate in the regulatory process or find basic information on existing and proposed regulations. The continued development of accessible, easy-to-understand regulatory information is a vital step. Moreover, the increased and innovative use of consultation with the general public would contribute to instilling greater trust in the regulatory system. Federal leadership that would bring industry and citizens' groups together to constructively discuss each other's concerns and explore solutions would be desirable. The report notes these issues are particularly evident in areas such as biotechnology/life sciences and environmental assessment.

Greater use of risk management principles – The federal regulatory framework continues to face greater demands to become more timely and transparent, while at the same time it is being constrained by limited capacity. The Committee observed that risk management principles are not being applied in a comprehensive and consistent manner and should become more prevalent in the review of regulatory frameworks for several sectors (e.g. environment assessment, and oil and gas exploration and development). By implementing risk management principles, the federal regulatory framework will focus on greater risks and achieve the intended outcomes of the regulations more effectively.

Increasing international regulatory cooperation – The Committee noted a lack of policy guidance as to when Canadian-specific regulations would be appropriate or when international regulatory cooperation would be preferable. The greater use of international cooperation would increase efficiency in the Canadian economy, continue to provide high levels of protection for human health and the environment and allow a more effective use of limited resources by regulators. These findings were particularly evident in areas such as the automotive and biotechnology/life sciences sectors, and the drug approval process.

1.1 Manufacturing and Product Approval

As a result of technological developments and ongoing efforts to liberalize trade, markets across the globe have become increasingly open and integrated. This has profoundly transformed the way in which companies do business, as they are continually innovating to develop new products to meet consumer needs, increase their market-share and cut production costs. The main competition for Canadian firms often comes not from other domestic manufacturers, but from foreign companies that operate under a different regulatory system than Canada's. Multinational corporations have restructured and consolidated their operations, resulting in the creation of a limited number of large and specialized plants that serve an international market and compete with one another for accessing intrafirm investment capital. Indeed, more than two-thirds of cross-border trade with the United States is intrafirm trade occurring between different parts of the same company operating on both sides of the border.

The regulatory system is perceived by many stakeholders as having an impact on Canada's investment climate. The Committee heard that, to succeed in this type of environment, Canadian firms need, among other things, dependable regulatory timeframes for planning their business activities and reliable access to necessary and new inputs. For example, in cases where Canadian standards for ingredients and final products differ from those of the international market, production in Canada could become less efficient, thus reducing Canada's attractiveness as a plant location.

Concurrently, citizens want assurances that safety, human health and environmental standards governing products are being maintained at a high level. Moreover, Canadians are demanding better accountability and transparency from both companies and regulators to demonstrate how these high standards are being met.

Within this context, increased regulatory efficiency will be able to both improve the competitiveness of these industries and ensure that the mandate to protect the health and safety of Canadians and the environment is respected. In addition, regulatory reform will assist regulators in helping to ensure that Canadian consumers have timely access to a wide range of products and the latest innovations at competitive prices.

1.1.1 Overview

The Committee heard from a variety of stakeholders across the country that Canadian regulatory standards which diverge from those of other jurisdictions, particularly the U.S., represent a key issue in manufacturing and product approval in a variety of sectors. Manufacturers can face differing requirements for products depending on whether they are made for sale within a province, interprovincially or internationally. These regulatory differences between Canada and its major trading partners can hurt Canadian economic competitiveness in terms of trade and investment opportunities.

Manufacturers have identified a number of regulations in Canada that affect their ability to access and use raw materials or that set industry standards for their products which they feel hinder innovation. In many cases, these regulations differ from the requirements of foreign markets, particularly those of the United States, which accounts for the vast majority of Canadian exports. Why do standards differ? The reasons include enhanced safety and quality standards, differing views on health promotion, different testing methodologies, different trade policy objectives and historical "artifacts" in regulatory approaches.

Examples of Canada/U.S. Regulatory Differences		
Issue	**Canadian Approach**	**U.S. Approach**
Antiperspirant deodorant	Aluminum content requires a Drug Identification Number (DIN).	No DIN required.
Trans fat on nutrition labels	In order to be considered "trans-fat free" a product must be below 0.2 g of trans fatty acids (i) per reference amount and serving of stated size or (ii) per serving of stated size if the food is a prepackaged meal.	In order to be considered "trans-fat free," a product must have less than 0.5 g per reference amount and serving size.
Fortification of breakfast cereals and other food products	Canadian regulations specify which foods may be fortified and the levels for their fortification with vitamins and minerals.	The U.S. has no limits on the levels of vitamins and minerals used to fortify food products.
Fortified water	Addition of vitamins and minerals to bottled water prohibited.	Bottled water may be fortified with vitamins and minerals.
Frozen pizza	BHA, BHT and caramel colour are approved additives but cannot be used in pepperoni and sausage chunks.	BHA, BHT and caramel colour are permitted for use in pepperoni and sausage chunks.
Cheddar-flavoured popcorn	Cheese seasoning must be less than 49% real cheese.	53% real cheese seasoning used.
Auto anti-theft immobilizers	Proposed requirement for immobilizers accepting Canadian and European standards.	An option for U.S. high-theft line vehicles.

The Committee feels that specific Canadian requirements should be limited to the following instances: there is no commonly agreed upon international or North American standard; important national priorities, unique Canadian circumstances or Constitutional values require a different approach; or the government has not yet developed sufficient confidence in the regulatory processes, practices results and/or decisions of a key trading partner to meet Canadian policy objectives. When specific Canadian requirements are adopted, the federal government should consider other tools at its disposal, including performance-based regulation and voluntary codes, to minimize the burden of specific Canadian regulatory requirements on businesses (see Part I, sections 3.1 "International Regulatory Cooperation" and 3.5 "Instruments for Government Action" for more details).

> **Recommendation 42: The federal government should work with stakeholders and citizens to develop an inventory of regulatory differences, particularly between Canada and the U.S., that impede Canadian competitiveness. They should be examined using the criteria for Canada-specific requirements. If regulations do not meet these criteria, Canada should take immediate action to align its regulatory requirements.**

The Committee examined regulatory compatibility and divergence regarding manufacturing and product approval in the following three fields: the automotive industry, the drug approval process and New Substances Notification (NSN) (e.g. chemicals).

1.1.2 Automotive Manufacture and Assembly

The Committee examined the automotive industry from the perspective of its North American structure and implications for regulatory cooperation. The automotive sector is the largest manufacturing industry in Canada, accounting for 13% of Canada's manufacturing GDP and has invested more than $23 billion in facilities and technology over the past decade.[12]

This industry is highly competitive, trade-oriented and fully integrated across North America. Canada is the eighth largest integrated vehicle producer in the world, assembling about 2.6 million vehicles annually and representing about 16% of North American vehicle production. A major portion of the vehicles manufactured in Canada are exported to the U.S. Similarly, vehicles assembled in the U.S. are freely exported to Canada.

At the same time, the Canadian automotive sector is facing increasing pressure from a number of fronts: increased competition from offshore manufacturers, over-capacity in companies' assembly plants, and regulatory pressures which auto companies have claimed are increasing their production costs. Moreover, the Canadian industry has witnessed the closing of three assembly plants in the past few years — with the associated loss of high-paying jobs — while a number of new plants were concurrently opened in the southern United States.

The Government of Canada's involvement in the automotive sector is derived from several cross-cutting mandates which include the safety of new and imported motor vehicles, environmental stewardship, the improvement of energy efficiency, the reduction of greenhouse gas emissions, and the fostering of the industry's international competitiveness and sustainable growth. Several federal departments (e.g. Transport Canada, Environment Canada, Natural Resources Canada) have a role in regulating or setting policies relevant to motor vehicles, the automotive industry and consumer interests.

For example, regulation and road safety are intertwined. With over 19 million vehicles on Canadian roads and over 21 million drivers operating vehicles across more than 900,000 kilometres of roads, road transportation is important to virtually every Canadian. In recent decades, deaths and hospitalizations due to motor vehicle traffic collisions have declined markedly in Canada. Since 1982, the road traffic death rate has declined by almost 50%, while the number of vehicles and licensed drivers on our roads has increased.[13] Nevertheless, road collisions continue to cost Canadians approximately $25 billion dollars annually.[14] Government interventions, such as laws mandating the use of seat belts and child restraints, as well as more stringent drinking and driving sanctions, public education and enforcement campaigns, safer vehicles and road infrastructure enhancements have all contributed to the increased safety of Canadian road users.

Government stewardship has also increasingly focused on the problem posed by greenhouse gas emissions from a variety of sources, including the transportation sector. According to Environment Canada, Canadians contributed about 720 megatons of greenhouse gases to the atmosphere in

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[12] Source: Canadian Vehicle Manufacturers' Association.

[13] Source: Transport Canada, *Road Safety: An Overview* (March 2004).

[14] Source: Transport Canada, *Road Safety Vision 2010: 2002 Annual Report* (March 2004). Figure varies depending on calculation method and does not include societal costs.

2001, up from 608 megatons in 1991. Of this amount, the road transportation sector[15] contributed 133.4 megatons (18.5% of the total), up from 107.5 megatons in 1990 (17.6% of the total). While emissions from the greatest number of vehicles — gasoline automobiles — actually declined during this time period, the overall growth of emissions in the road transportation sector is primarily attributed to an increase in the number of light-duty gasoline trucks (such as SUVs and mini-vans) and heavy-duty diesel vehicles.[16]

It should be noted that in both Canada and the U.S., compliance with regulated performance requirements is based on a self-certification regime applied by the companies themselves. However, both countries exercise safety oversight through testing, auditing and investigations.

Key Challenges

Automotive regulations fall under four types: fuel consumption standards; safety regulations; emission regulations; and fuel quality standards. They affect mostly those vehicles which are sold in Canada, irrespective of their country of manufacturing. Since more than 85% of vehicles sold in Canada are produced abroad, auto regulations in Canada have implications not only for Canadian assemblers but also for assemblers manufacturing in other countries.

The Government of Canada strives to harmonize regulatory requirements and policies with those of the U.S., except in cases where there is a benefit to Canadians in pursuing a non-harmonized approach. In such cases, departments have indicated that they attempt to make every effort to develop regulations and policies that are as compatible as possible with those of the U.S. to permit the sale of vehicles in either market, while placing a high priority on safety and environmental responsibility.

Approximately 85% of existing Canadian safety standards for new motor vehicles are harmonized with those of the U.S. However, North American manufacturers have expressed concern that there may be an increasing trend towards regulatory divergence in areas that could complicate vehicle design, engineering and manufacturing processes.

Canada-U.S. Regulatory Divergences

There are areas in which Canadian and U.S. automotive standards vary or could diverge under new regulatory initiatives:

1. Transport Canada has Canadian requirements in the Frontal Occupant Protection Safety Standard (Canada Motor Vehicle Safety Standard 208) and is proposing new requirements that would not be harmonized with those in the U.S. These proposed changes will require that seat belt and air bag systems be optimized to provide protection for occupants who are wearing seat belts. The intent of the new regulation is to give Canadians the highest practicable level of protection and to minimize the risk of air bag-induced injury, particularly among children and short-statured drivers. This Canadian-specific regulation is based on the higher seat belt usage rates in Canada, compared to the U.S., and the desire to provide optimal protection to these belted occupants.
2. As part of Canada's Climate Change Plan 2000, it was proposed by the federal government that vehicle manufacturers voluntarily improve fuel efficiency standards by 25% by 2010. The changes have been proposed in the context of Canada's Kyoto Accord obligations to lower emissions. Such a target would significantly diverge from Canada's current fuel-efficiency alignment with the U.S.
3. There are other existing divergences (e.g. front daytime running lamps, 5 mph bumpers in Canada versus 2.5 mph in the U.S. — the result of the U.S. downgrading its requirements in the 1980s) and proposed divergences (e.g. anti-theft immobilizers on new vehicles, and trailer rear under-ride protection). While there are valid reasons for each of these unique requirements, the issue of the cumulative impact of all divergences remains.

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[15] This sector consists of gasoline automobiles, light-duty gasoline trucks, heavy-duty gasoline vehicles, motorcycles, diesel automobiles, light-duty diesel trucks, heavy-duty diesel vehicles, and propane and natural gas powered vehicles.

[16] Environment Canada, *Canada's Greenhouse Gas Inventory - Overview 1990-2001* (October 2003) pp. 4-5.

One of the challenges for industry is that these changing regulatory requirements have to be factored into the vehicle design process. Vehicle designs have a lifespan of 5 to 15 years, with designs locked in as much as 4 years in advance of production. Accordingly, manufacturers have stated that they require significant lead time (at least six years) to implement regulations and adequate flexibility to implement regulatory change in terms of human resource and capital allocations (although it should be noted that regulators factor in lead time when consulting with industry on regulatory proposals).

As an alternative to accomplishing public policy objectives through vehicle design changes, there may be other instrument options that could accomplish similar results. For example, rather than pressing for across-the-board fuel efficiency and emissions improvements, the government could provide incentives for consumers to purchase smaller, more efficient vehicles which are already on the market or disincentives to purchasing larger, less efficient vehicles.

These proposed changes to vehicle design resulting from Canadian regulatory requirements may have a longer-term impact on the health of the industry. Investment decisions are based on a variety of factors, regulatory differences being among them. Given the competitive global environment, these differences may leave the impression with potential investors that Canada's regulatory system is overly complex, hampering the international perception of Canada's business climate.

The Committee recognizes the challenges the automotive industry faces to retain and attract investment while respecting the need to maintain the integrity of safety and environmental standards, which benefit all Canadians. Accordingly, given the roles of multiple federal regulators and the impact of this sector on the Canadian economy and environment, the Government of Canada must develop a policy framework to outline its policy goals for the automotive sector. In so doing, the government could then align its regulations to ensure they help achieve these policy priorities.

The Committee feels that such a framework would help create a new and modern automotive regulatory environment, address Canadian economic concerns (e.g. domestic investment and employment in Canada), foster the automotive manufacturing industry's ability to innovate and compete globally, and protect the health and safety of Canadians and the environment.

> **Recommendation 43: A comprehensive Canadian automotive policy framework is required in order to coordinate automotive regulatory roles and develop clear objectives. This framework would also incorporate a strategy of cooperation on standards and joint regulatory development with the U.S.**

1.1.3 Drug Review Process

Canada, like other industrialized nations, faces significant challenges with respect to the regulation of new drugs. Key issues for Health Canada include keeping up with the fast pace of scientific discovery that leads to the development of new drugs, and responding to consumer demands for access to innovative and potentially life-saving medicines.

The process of making these medicines available on the Canadian market is complex and involves decisions by a number of parties. The Committee agrees with Health Canada and its partners that safety is paramount. It has also heard, however, that the processes to approve and make these new medicines available to Canadians take too long. This delay can lead to lost sales for pharmaceutical companies, resulting in disincentives for the development of new pharmaceuticals in Canada and lost opportunities for innovation.

There are three main factors involved in approving and making new drugs available to Canadians, all of which should be considered in an overall drug strategy.

The first is the marketing strategies of pharmaceutical companies. In general, new drugs are introduced to Canada, which represents 2% of world pharmaceutical sales, only after they have been sold in other larger markets for several months or even years. Seventy percent of new drug submissions are filed first in the United States, where pharmaceutical companies can expect to recuperate their research and development costs more quickly. The second factor is the inclusion of new drugs in provincial formularies, a process which entitles citizens to be reimbursed for these drugs under their provincial health care plans. The third factor is the drug review process under the responsibility of Health Canada, which faces pressure to ensure the safety of new therapeutic products but to do so more quickly and efficiently.

The Committee decided to focus its recommendations on how international regulatory cooperation can improve Canadians' access to new drugs by speeding up the drug approval process, thereby enabling Health Canada to use its limited resources more strategically. If Canada's regulatory process were more closely aligned with the processes of leading countries in the area of drug review, then safe products already approved in those countries could be introduced more rapidly to the Canadian market. Canada could implement such an approach by adopting international standards and streamlining the review process for medicines previously approved in other countries with high regulatory standards.

Key Challenges

A Slow Drug Approval Process

Under the *Food and Drugs Act*, Health Canada is responsible for the review of drugs authorized for sale in Canada, a process which involves assessing their safety and quality. The drug review process comprises three distinct but interrelated stages, the first of which is the scientific review of new drugs. The second stage entails regulating the quality of both the manufacturing installations and processes for drugs. Lastly, Health Canada is responsible for continually monitoring the safety and quality of drugs after they have been released on the market.

Between January 1999 and June 2003, Health Canada's Therapeutic Products Directorate received and processed 314 applications for new drugs. These are drugs containing a substance that has not been sold in Canada for a sufficient length of time and in a sufficient quantity to establish its safety and effectiveness.[17] Over half of these applications involve changes made to previously approved drugs, such as changes to the combination or proportion of ingredients, or the formulation of the finished product (including dosage, presentation and labeling). Over this period, 139 submissions (less than half) involved new active substances (i.e. substances never previously approved for sale in Canada).

Although target review times for new drugs in Canada compare with those of other countries, they are met only a small proportion of the time. The Centre for Medicines Research International indicates that Canada's review performance times lag behind those of the U.S., Switzerland and the EU, are more or less on par with Australia's, and are ahead of Japan's.[18]

With respect to new active substances, in 2001–2002, pharmaceuticals were introduced to the Canadian market on average six months later than in the U.S. In the case of biologics, the delay relative to the U.S. market ranged from six months to two years.

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[17] Data provided by Health Canada's Therapeutic Products Directorate based on the *Annual 2002 Drug Performance Report.*

[18] Centre for Medicines Research International, R&D Briefing #35, *The Impact of the Changing Environment on Review Times.*

This delay can be explained in part by the fact that, in 2001–2002, industry filed applications for regulatory review of new active substances in the U.S. before it did so in Canada. On average, filings for pharmaceuticals took place 3 months later in Canada than in the U.S., while they occurred 12 months later for biologics. The delay in question is further compounded by the fact that, in 2001–2002, the regulatory review and approval of pharmaceuticals and biologics (new active substances) required, on average, four months more in Canada than in the U.S.[19]

In addition to these factors, it has also been argued that drug companies may often decide to introduce these drugs to the Canadian market later than in the U.S., following the respective drug approvals in the two countries. In order to ensure that Canadians have timely access to new drugs, the Canadian regulatory process has to take these market realities into account and adapt accordingly.

In terms of meeting its own performance targets, Health Canada reports that, for 2002, the average time to first decision[20] for pharmaceuticals was 547 days for approved non-priority new active substances submissions (192 days over the performance target time), and 332 days for approved priority new active substances submissions (97 days over the performance target time). For 2003, approved non-priority new active substances submissions took an average of 678 days, while approved priority new active substances required an average of 348 days.[21]

Regulatory performance targets are also an issue for the generic drug industry as well. According to Health Canada, in 2002 the average time to first decision for generics was 368 days (133 days over the performance target time of 235 days). In 2003, the average time to first decision was 385 days (150 days over the performance target time).[22]

Delays in the drug review process are due in large part to a backlog (applications for which the performance target has not been met) that applied to an estimated 60% of all drugs and biologics under review by Health Canada until last year. Health Canada reports that the 2003 increase in approval times stems from efforts to reduce this backlog, leading to a 62% reduction in the pharmaceuticals backlog as of March 2004 (relative to March 2003). Moreover, the department plans to have the pharmaceuticals backlog eliminated entirely by the end of 2005–2006. Through its Therapeutic Access Strategy, Health Canada has also revamped its drug review processes to incorporate practices contributing to the high level of performance at the U.S. Food and Drug Administration (FDA). With the progressive elimination of the backlog, Health Canada can focus on implementing practices that reflect the principles of Smart Regulation: making the drug approval process simpler, more efficient and focused on quality of results.

A slower approval process does not necessarily indicate greater rigour in the scientific review of new drugs. Instead, it can reflect the effects of the regulator's limited resources and capacity. For example, the U.S. has a higher rate of products withdrawn from the market than Canada,[23] but this is due in part to new pharmaceuticals often being approved in the U.S. before being submitted for review in Canada. This time lag allows Canadian authorities to consider post-market data in their scientific review, thereby reducing the number of withdrawals.

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[19] Data provided by Health Canada's Therapeutics Products Directorate.

[20] "Time to first decision" refers to the time period from reception of a submission by the Therapeutic Products Directorate to first response, which

could be either a Notice of Deficiency, Notice of Compliance or Notice of Non-Compliance.

[21] Data from Health Canada, Health Products and Food Branch, *Annual Drug Submission Performance Report - Part I: Therapeutic Products Directorate (TPD), 2003.*

[22] Health Canada, Health Products and Food Branch, *Annual Drug Submission Performance Report – Part I: Therapeutic Products Directorate (TPD), 2003.* In the report, generic drugs fall under the category of "Abbreviated New Drug Submissions" or ANDS.

[23] The actual proportions are relatively low in both cases: 3.1% of products for the U.S. compared with 1.8% of products for Canada.

It should be noted that industry sources have reported longer approval times compared with data provided by Health Canada. These differences highlight the challenges of measuring and reporting information about the drug review process clearly and consistently.

Using Limited Resources More Wisely

Canada needs to recognize that its resources and capacity are limited compared with those of other leading regulatory authorities, such the U.S. Food and Drug Administration. For 2002, the FDA's budget for the evaluation of human medicines reached an estimated $US220 million, as compared with Health Canada's $US40.9 million. The FDA also deploys 10 times more people for drug reviews than Health Canada, resulting in roughly the same number of new drugs approved as in Canada. However, the FDA's performance surpasses that of all other jurisdictions with regards to the quality of its scientific review and the speed of its approval process.

Canada cannot support a regulatory agency as large as the FDA, nor can it afford to carry out drug reviews as extensive as those of its American counterpart. It must be strategic in the use of its limited resources. It can do this by focusing on areas where products are specific to the Canadian market (such as blood-derived products, vaccines, etc.), or where Health Canada can demonstrate that an independent review process is essential to the health and safety of Canadians. The strategic use of resources also means taking advantage of the regulatory knowledge and capacity developed in other jurisdictions, such as using data and results from reviews carried out elsewhere, sharing workloads and processes, and eventually establishing mutual recognition or accepting the equivalency of processes. Although shaped by a particular context, the European Agency for the Evaluation of Medicinal Products (EMEA)[24] is an example of taking a single window approach to the regulation of therapeutic products. Simply put, if 25 European countries can work in a cooperative multilateral framework to assess drugs, why can't Canada participate more fully in international approaches?

Increased international cooperation in the review of new drugs can lead to direct benefits for citizens in terms of accelerating the introduction of safe new therapeutic products to the Canadian market. Better and more strategic use of international cooperation would also allow Health Canada to allocate resources more efficiently to areas which require a Canadian approach and could provide advantages to the country. For example, the department could devote additional resources to working more closely with industry stakeholders in the research and development of innovative therapeutic treatments, as the FDA does. Resources could also be shifted to such areas as developing clinical trials in Canada and post-market monitoring of adverse drug reactions, as outlined in Health Canada's Therapeutic Access Strategy.

Using International Cooperation More Strategically

Health Canada is currently involved in a number of international cooperation agreements with the U.S. and other jurisdictions. However, it needs to move forward more rapidly on strengthening and implementing its international cooperation framework. Strategic international regulatory cooperation involves determining when and with whom to collaborate in order to increase the efficiency of the drug review process and generate benefits for Canadians. This includes determining when it makes more sense to align our regulatory process with the processes of our trading partners (i.e. Canada adopting international standards or accepting equivalency), and when we should develop mutual collaboration (e.g. joint or shared review processes).

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[24] The EMEA carries out the regulatory approval on behalf of the entire European Union for medicinal products based on biotechnology only. The majority of conventional medicinal products are approved at the national level and these approvals are mutually recognized by other member states within the EU. If an EU state refuses to recognize the original approval of another EU state, the points of dispute are submitted to the EMEA for arbitration.

International regulatory cooperation can take a variety of forms, as discussed in Part I, Section 3.1 "International Regulatory Cooperation." The Committee believes that both long-term and short-term objectives for cooperation should be developed.

In the short term, Health Canada should focus on determining the areas of the drug approval process for which an independent approach does not contribute to the quality of decisions or generate a benefit for Canadians. For example, alignment with other regulatory authorities could be considered for applications involving changes to a therapeutic product that are minor or do not require scientific review. Another example is in the area of manufacturing data reviews, where pharmaceutical plants comply with quality standards that are accepted by many different regulatory authorities around the world. Could these international standards not be accepted by Canada as well, thereby reducing the need for independent review? Pre-market reviews and post-market surveillance are other areas where Canada would benefit from increased international cooperation without compromising control over outcomes. A recently signed Memorandum of Understanding between Health Canada and the FDA for new therapeutic advances, such as cell and gene therapies and medical technologies, illustrates this approach.

A comparative outcomes-based review of new drug submissions over the past five years between Canada, the U.S. and the EU could help determine the substantive differences in their respective approval processes and whether these differences could result from the analysis of post-market surveillance information alone. It would also be useful to examine new drug submissions made over the past five years to the FDA and the EMEA, but not to Health Canada, to determine potential lost benefits to Canadians from the unavailability of these medicines. This analysis would indicate both the potential benefits of independent Canadian drug review (for example, enhanced safety in the case of products withdrawn from the U.S. market but never introduced in Canada) and the costs associated with deferred access to innovative therapeutic products. Based on this analysis, Health Canada could consider how and when to better align itself with other jurisdictions that have high regulatory standards.

Longer-term objectives should be developed to maximize the benefits for Canadians of the knowledge and regulatory capacity developed in other jurisdictions. Canada needs to determine when common regulatory challenges could best be addressed through international cooperation. For mutual cooperation to take place, other countries will need to develop confidence in Canada's regulatory assessment capabilities and vice-versa, which can be achieved through confidence-building measures (see Part I, Section 3.1 "International Regulatory Cooperation"). Ultimately, Health Canada should aim to develop relationships of confidence with comparable regulatory authorities that would allow it to accept the decisions of other jurisdictions under certain circumstances.

Recommendation 44: The federal government should further develop its international cooperation framework for the regulation of therapeutics to include short- and long-term objectives and timeframes, and it should proceed quickly with the implementation of this framework to achieve a level of performance reflecting international best practices.

Recommendation 45: The federal government's short-term efforts should be focused on implementing measures to use data and reviews produced in other jurisdictions when an independent Canadian process does not add to the quality of outcomes. Longer-term efforts should focus on establishing mechanisms to maximize the benefits for Canadians of the knowledge and regulatory capacity developed in other jurisdictions in order to provide timelier access to new therapeutic products.

Indemnification of Officials

Health Canada, and the government in general, can be sued for acts or omissions committed by its staff. This has an impact on the organizational culture and can contribute to resistance to change and risk aversion, particularly in light of increasing therapeutic product-related litigation involving the government. Providing some measure of immunity to a regulatory authority and its individual staff members may be appropriate in some circumstances, such as when the regulator is undertaking its responsibilities for the benefit of the public in general.

Other leading regulators, such as the U.S. Food and Drug Administration and Australia's Therapeutic Goods Administration, provide some measure of immunity from litigation where they can demonstrate that their duty to the public was fulfilled.

Price Controls on Non-Prescription Drugs

Under the *Patent Act* and the *Patented Medicines Regulations*, the Patented Medicine Prices Review Board (PMPRB) protects consumers against excessively priced patented medicines. Although "medicine" is not defined in the Act, a substantial body of related jurisprudence combined with the PMPRB's definition of "medicine" in its guidance documents captures pharmaceutical products that are subject to marketing approval by Health Canada. Within this group of products, the Act does not distinguish between prescription and non-prescription drugs and neither does the PMPRB.

At present, there are a number of non-prescription drug products under the PMPRB's jurisdiction. An association representing some manufacturers of non-prescription drugs has argued for some time that non-prescription (over-the-counter) drug products should be exempted from price controls or regulated under a complaints-driven framework in order to reduce any burden of compliance. They also claim that these products appear to operate in an open competitive consumer market where consumers themselves choose to buy or not to buy a product.

In considering whether action is warranted, a first issue is to clarify where policy responsibility lies in this matter. The *Patent Act* is part of the portfolio of the Minister of Industry. However, the Minister of Health is designated under section 79 of the Act as the Minister responsible for the purposes of sections 79 to 103 of the Act (i.e. the sections that give rise to the PMPRB). The Minister of Industry, therefore, would make legislative changes to the PMPRB's mandate only on the advice of, or in conjunction with, the Minister of Health. Similarly, while the PMPRB establishes its operational guidelines and procedures, and can make recommendations for regulatory amendments, the authority for changes to the *Patented Medicines Regulations* lies with the Minister of Health. Thus, if legislative or regulatory changes to the provisions in the *Patent Act* relating to the PMPRB were required, action by the Minister of Health, in conjunction with the Minister of Industry or the PMPRB as appropriate, would be necessary.

Clarifying roles, responsibilities and accountability is an important step in increasing transparency. Identifying a single point of contact for stakeholders could also be desirable if proven to be feasible.

Recommendation 46: Health Canada and the Department of Justice should explore and recommend, in the context of the renewal of the *Food and Drugs Act* and other health protection statutes, what immunity might be appropriate to the department and its staff. The recommended approach should be consistent with the protection provided to other leading therapeutic product regulators, including the U.S. Food and Drug Administration and Australia's Therapeutic Goods Administration.

1.1.4 New Substances Notification

The chemical manufacturing industry is an important component of the national economy as chemicals are the basic building blocks for many Canadian industries. The chemical industry is the fourth largest manufacturing sector in the country and sixth overall as a creator of wealth in Canada's economy. Canada's chemical industry employs 83,000 Canadians, providing highly skilled and well-paid jobs relative to other sectors of the Canadian economy.[25]

Canada's regulations for this sector are embodied in the *Canadian Environmental Protection Act, 1999*, which is intended to contribute to sustainable development through pollution prevention and to protect the environment and human health from the risks associated with toxic substances. Under CEPA 1999, the *New Substances Notification Regulations* ensure that no new substance is imported into or manufactured in Canada without a formal "cradle to grave" review of its potential risks to human health and to the environment.

Under CEPA 1999, a substance is considered "new" if it does not appear on the Domestic Substances List (DSL).[26] Using information provided by notifiers and other available information, Environment Canada and Health Canada conduct a joint assessment to determine the risk that the substance may pose to the environment and human health. Risk management measures are implemented in the event they are required. Assessments usually take from 5 to 90 days.

Key Challenges

Given the size and dynamics of the U.S. marketplace, most new chemicals in North America are developed in the U.S. Although there is considerable sharing of assessment information between regulators in Canada and the U.S., each country maintains a separate regime for the assessment of new chemical substances. As such, chemicals approved for use in the U.S. have to undergo separate assessments in Canada, and vice versa. In an integrated North American market, this can negatively impact the competitiveness of not only Canadian primary chemical manufacturers, but also processors who incorporate chemicals into consumer and industrial products. Chemical companies increasingly serve a North American and world market and regard different national regulatory regimes as non-tariff barriers to trade. They want access to an inventory of chemical inputs that they can use and ship anywhere.

The Canadian new substance regime places the onus on notifiers to provide the required test data and other assessment information needed to evaluate the chemical. The regime ties the amount and type of test data to the proposed volume, associated risk and potential for exposure of the products. If any of the requested test data are not necessary or feasible to obtain, the requirement can be waived, something that is done frequently. The test data, analysis from predictive modeling and all other publicly available assessment information are used by Environment Canada and Health Canada to assess the potential toxicity of the substance and its likely effects under different exposure scenarios.

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[25] Canadian Chemical Producers' Association, *Canada's Chemical Industry: A Keystone to the Canadian Economy*, p. 9.

[26] The DSL is a comprehensive compilation of all known substances falling within the scope of the NSN regulations that were in commercial use in Canada between January 1, 1984 and December 31, 1986, or that have subsequently been fully notified and assessed under CEPA 1999 and the NSN regulations. Accordingly, substances that are listed on the DSL are exempt from any reporting requirements under the NSN regulations.

The Toxic Substances Control Act (TSCA), administered by the U.S. Environmental Protection Agency, requires test data from industry only if they are already in the possession of the notifier. In the majority of notifications, the U.S. EPA supplements this data through the use of computer modeling when assessing potential health and environmental effects. Another way in which the U.S. approach differs from the Canadian one is the requirement under the TSCA to show that a chemical presents or will present an "unreasonable" risk in order to regulate it.

While there is support for the current policy among many Canadian stakeholders,[27] some representatives within the Canadian chemical sector argue that Canada should generally accept the results of U.S. assessments unless uses/exposures of the chemical in question are different in the two countries. Until there is greater availability of U.S. assessment documentation and information, the federal government's position is that it has chosen not to follow this approach because it believes that it cannot respond to calls for greater accountability to the Canadian public and because there remains significant uncertainty whether such an approach would result in an unacceptable and lower level of environmental and human health protection.

The Committee has heard conflicting views over whether the differences between the two new substances regimes have impeded Canadian industry's access to new chemicals despite the large difference between the two countries' domestic inventories (80,000 chemicals in the U.S. compared with 23,000 in Canada). On the one hand, the larger inventory of available chemicals in the U.S., relative to Canada, appears to be more a function of several factors: the size and diversity of the countries' chemical industries; the number of grand-fathered, unassessed substances in the U.S.; and when and how the inventories were created and how they are updated (e.g. new substances that are available for use do not get added to the Canadian domestic substances inventory until a particular volume threshold is reached). On the other hand, chemical industry representatives claim that the NSN regulations cause delays for the Canadian industry in obtaining access to new chemicals, a situation which they say damages the competitiveness of their sector.

It should also be noted that, in some cases, Canada does use American assessments in Canadian decision making. The Non-Domestic Substance List (NDSL) largely consists of substances that are not on Canada's DSL, but are in commercial use in the U.S. When a substance is added to our NDSL, it faces reduced reporting requirements in Canada. Under the Canada-U.S. Four Corners Agreement (see below), a company submitting a chemical to the U.S. EPA for review can also request that its data and assessment results be shared with Canada. Moreover, as a result of the recent NSN regulations review, the waiting time for adding a substance to the NDSL is intended to be reduced from five years to one year. Environment Canada should ensure that it meets its commitment to have these regulatory changes in place by early 2005.

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[27] For example, the ongoing revisions to the NSN regulations are largely guided by consensus recommendations produced by a multistakeholder group consisting of representatives from the federal government, industry and public advocacy groups. Please see: Health Canada and Environment Canada. *Consultations on the CEPA New Substances Notification Regulations and New Substances Program: Final Report of the Multistakeholder Consultations*. December 2001.

Ongoing Canada-U.S. Cooperation

The Committee finds it highly encouraging that both Canada and the U.S. have recognized the importance of bilateral cooperation in achieving greater efficiencies in the introduction of new substances to the North American marketplace. Canada and the U.S. have a history of collaboration through information sharing in this field. Since it is not in the public interest for national agencies to duplicate each other's efforts, the responsible agencies are working towards introducing new chemicals to the marketplace more efficiently while assuring the protection of public health and the environment.

This cooperation is embodied in the Canada-U.S. Four Corners Agreement, which involves Canadian and U.S. federal regulators and chemical industries in both countries. Its objectives include increased mutual understanding of the risk assessment and risk management policies and practices in both countries, identification of strategies for overcoming barriers to greater cooperation, and identifying and taking appropriate action to ensure progress toward the long-term goal of greater cooperation and alignment of Canadian and U.S. new substances regulatory schemes.

Canadian and U.S. regulators are working towards a shared vision that could be considered as embodying Smart Regulation approaches where:

- each country can see, understand and accept each other's results aimed at protecting human health and the environment;
- companies can submit one notification (assessment dossier) and then, after national review, market anywhere in North America;
- chemicals approved for use in North America would be routinely accepted in commerce by other OECD countries; and
- countries and companies can make better use of their assessment resources and continuously improve their decision making concerning new chemicals.

The Canadian government is putting an action plan in place to pursue this vision. To make the vision a reality, each government would have to document its assessment decisions in a way that can be shared with the other country's regulatory agency. The industries in both countries would have to support changes to the ways in which confidential and proprietary business information is protected, which has been a substantial stumbling block to promoting broader Canada-U.S. cooperation in this field. The Committee supports this approach.

The Committee also endorses Canada's efforts to promote the use of Mutual Acceptance of Notifications (MAN) with the United States and internationally. As the first step towards this goal, companies would be able (but not compelled) to notify under a MAN process. They would authorize intergovernmental sharing of their assessment dossier and, where warranted, augment their notified information. The first country notified would then review the notified substance, fully conduct the hazard assessment, and document and share the results. Other countries when in receipt of such information would agree to use it in their risk assessment process. All countries would have to put in place measures for the effective and secure sharing of assessment information and for the protection of confidential business information. Rather than each country doing its own exposure and risk assessment and comparing the outcome to what another country has done, an equivalency framework would also be adopted. This framework would provide a decision tree justifying why a separate or new exposure and risk assessment may or may not be necessary.

A MAN with Europe, which is currently proposing major revisions to its chemical regulation, would provide considerable assessment information for use by both the new and existing chemical program. That said, the Committee recognizes that the development of a MAN with the European Union or other international jurisdictions will take considerable time and effort to implement.

These signs of progress are important as the Committee holds the view that Canada ought to eventually be able to rely on another regulator's hazard assessments. After all, a toxic chemical will have the same effect of humans, plants and animals no matter where it is released. What differs from country to country is the amount released and what is going to be exposed. Other important factors that must be taken into consideration are the duty of care and burden of proof imposed by a country's legislature and the different scope of the legislation itself. ◆

1.2 Biotechnology/Life Sciences

The industrial revolution changed the world. Developments in the life sciences sector will likely have the same impact. Recent scientific discoveries have significantly increased our ability to develop new knowledge and innovative products and processes such as pest-resistant crops with higher yields, better disease diagnostic tools, and treatments that complement one's genetic make-up. The life sciences sector is research-based and capital-intensive and could yield positive benefits in such fields as health care, the environment, safety, agriculture, aquaculture, economic development, food safety and sustainable development.

This section addresses issues related to biotechnology. The Committee is of the opinion that the analysis is relevant to other emerging multidisciplinary areas such as nanotechnology. Given the highly complex and broad nature of biotechnology, the Committee decided to limit itself to certain issues: a regulatory strategy for biotechnology, legislation, international cooperation, and communications and stakeholder engagement. Other important questions including environmental and ethical issues that could affect the nature of the future regulatory framework were not researched in detail and were not included in the Committee's work plan.

Canada is internationally well positioned in this field, as it now accounts for almost 10% of the world's biotechnology-related revenues and ranks second behind the U.S. in number of biotechnology firms. The federal government has made significant efforts and investments to support the development of biotechnology. In 1998, it released the Canadian Biotechnology Strategy, which has so far formed the basis of federal government action. Various committees were also established to oversee the development and implementation of the broad policy issues associated with biotechnology. The most notable of these is the Biotechnology Ministerial Coordinating Committee (BMCC), which includes the ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade. The Canadian Biotechnology Advisory Committee (CBAC) was also created to provide external advice to government.

The federal government has allocated significant resources to biotechnology over the past few years. In 2002–2003, it invested $695 million in science and technology expenditures on biotechnology[28] (up 25% from 2001–2002), which includes the $9 million earmarked annually for the Canadian Biotechnology Strategy since its creation. Of this $9 million, $2.5 million is allocated to the CBAC, $0.5 million to the operations of the Canadian Biotechnology Secretariat,[29] and the remaining $6 million to the Canadian Biotechnology Strategy Fund to support departmental initiatives.

From policy and regulatory standpoints, biotechnology falls under the mandate of many departments, including Health Canada, the Canadian Food Inspection Agency and Environment Canada. Health Canada regulates biotechnology-derived products that are subject to the *Food and Drugs Act*, that is, genetically modified and other novel foods, biologics, assisted human reproduction technologies and therapeutics. The department also regulates pest control products as they relate to human health and the environment under the *Pest Control Products Act*. In turn, the CFIA regulates biotechnology-derived products including plants, animal feeds and animal feed ingredients, fertilizers and veterinary biologics, and conducts all federal inspection and enforcement services related to food — including those stemming from the *Food and Drugs Act*. Finally, under the *Canadian Environmental Protection Act, 1999*, Environment Canada and Health Canada regulate all new substances except new substances for uses that are regulated by other federal acts and regulations that include environment and health risk assessments. These are listed for biotechnology products under schedule 4 of CEPA 1999.

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[28] Source: Statistics Canada. Ninety-five percent of the federal biotechnology expenditures were devoted to R&D. These statistics exclude regulatory activities of the federal government.

[29] The Secretariat reports to the BMCC. Its two main functions are to coordinate horizontal decision making across departments and to provide secretariat services for the CBAC.

Other federal departments have important responsibilities regarding policy, research and regulatory issues that affect biotechnology-derived products. These departments include Agriculture and Agri-Food Canada, Industry Canada, Justice Canada and the National Research Council of Canada.

1.2.1 Key Challenges

Despite federal actions to support biotechnology, the Committee believes that significant challenges remain. The 375 biotechnology firms located in Canada[30] face serious obstacles, including accessing early stage financing and conducting the R&D required to commercialize their ideas and grow their businesses.

The development of biotechnology in Canada is also hindered by increasingly complex regulatory challenges. Current legislation, which was largely developed before the advent of biotechnology, is often ill equipped to address these challenges. Regulators must also evaluate large numbers of products of a more and more complex nature. These products will increasingly be multifunctional (e.g. nutraceuticals), based on converging scientific disciplines (e.g. nanotechnology for drug delivery), or use plants and animals to produce drugs and vaccines. In addressing these challenges, the federal government will want to consider how best to take advantage of Canadian investment in research and development capacities and also establish relationships with scientific communities, for example, universities, centres of excellence and granting councils. Government must also address the ethical issues often associated with biotechnology.

If Canada is to be a successful leader in biotechnology, it is particularly critical that Canadians' views and concerns be given due consideration in the policy and regulatory development process. This means that government must address not only scientific considerations but also ethical issues in a transparent and inclusive manner. This part of the process is critical, as public trust is essential to a successful regulatory system.

Recent surveys[31] demonstrate that Canadians generally tend to support areas of clear benefit to them, but only a very small percentage of Canadians consider themselves to be very familiar with biotechnology. Thus, another key challenge for regulators is to inform consumers about products derived from biotechnology and to engage them when they develop regulation in this area.

In an environment where a number of departments share regulatory responsibilities, accountability is at times unclear and collaboration is not always effective. This situation can lead to regulatory frameworks, decisions and enforcement which are not always coherent and integrated.

Biotechnology has often been identified as a national priority. However, the Committee did not see clear evidence of this. There is a need for effective leadership and accountability, both of which are required to ensure a concerted federal approach to biotechnology regulation and the timely attainment of federal regulatory objectives. In addition, there are still significant legislative and information gaps and outdated legislative frameworks, which affect the commercialization of and access to biotechnology products. More efforts could also be devoted to informing and engaging the public concerning biotechnology issues.

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[30] The latest data available from Statistics Canada date back to 2001

[31] Public opinion research into biotechnology issues. Earnscliffe/Pollara. December 2003

Federal Biotechnology Regulatory Strategy

Consultations leading to the development of the 1998 Canadian Biotechnology Strategy (CBS) revealed, among other things, the need for better coordination within government to address issues affecting many departments. This feedback translated into 10 CBS work plan themes. One of these concerned the need for continuous improvement in the regulatory system to accommodate the growing demands of new applications of biotechnology; another concerned modernizing Canada's intellectual property laws. The Biotechnology Ministerial Coordinating Committee was mandated to oversee the strategy's implementation and address multidepartmental issues. Unfortunately, the strategy did not translate its proposed policy framework into a work plan with clear timelines and accountability; it only listed "possible actions." Its progress is therefore difficult to measure.

Six years later, despite the establishment of several governmental and industry committees to shape the federal approach to developing and applying biotechnology, there does not seem to be effective and accountable leadership in Canadian biotechnology regulatory matters. The BMCC, which comprises seven ministers, has met only once since it was created. However, senior officials responsible for biotechnology have been active, producing among other things a recent federal proposal to strengthen Canada's position as a responsible world leader in biotechnology. This proposal, which is under consideration, addresses how best to balance the detection and management of risk with the development and commercialization of new discoveries to capture health and environmental benefits for Canadians.

> **Recommendation 47: The government should make it a priority to develop and implement a comprehensive, government-wide biotechnology regulatory strategy which would:**
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> - **identify and address legislative gaps, implement systematic international cooperation, and provide accessible and comprehensive information about regulatory developments;**
> - **identify ways to access and draw from the expertise of the domestic and international scientific communities;**
> - **give due consideration to ethical issues;**
> - **provide opportunities for input from all stakeholders and for citizen engagement;**
> - **be translated into a detailed work plan that measures and reports on progress;**
> - **be reviewed regularly and modified to account for progress in implementation and the rapid changes that characterize biotechnology; and**
> - **assign clear and effective accountability for its strategic leadership and management.**

It should be noted that many of the above issues were previously highlighted by other external bodies.[32]

Legislative Gaps

Canada needs a clear legislative framework for biotechnology if the public is to benefit from biotechnology products and if firms are to research, develop and commercialize new products. Without such a framework, Canada will have much more difficulty attracting financial and scientific resources. The federal government must address all current and future gaps in biotechnology legislation in a timely fashion. When doing so, it should ensure appropriate expert input and public involvement.

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[32] Royal Society of Canada Expert Panel on the Future of Food Biotechnology, *Elements of Precaution* (February 2001); Canadian Biotechnology Advisory Committee, *Improving the Regulation of Genetically Modified and Other Novel Foods and Feeds* (August 2002).

Stem cell research illustrates an area where a legislative vacuum has existed for many years. Stem cells can be cultured from certain types of tissue such as embryonic or fetal tissue. Such research holds great potential to treat human disease, including Alzheimer's, Parkinson's, diabetes, multiple sclerosis and heart disease. After more than a decade of work on a legislative framework for this area, a bill providing a legislative framework for stem cell research received Royal Assent on March 29, 2004.[33] The Act will have a staged implementation. In that same time, most other developed countries have implemented their own regulatory frameworks. Some, such as Germany and Ireland, have banned embryonic research, while others, including the U.K., Japan and Israel, have opted to allow the creation of embryos for research. Lack of regulation leads to the potential for unethical research and creates market uncertainty.

A number of legislative gaps currently exist, including:

- *Biotechnology products regulated under health statutes*: The current health statutes are decades old and do not provide an appropriate legislative framework for products that are new and novel, have characteristics of both food and drugs or are targeted at a narrow sub-group of the population, such as pharmacogenomics. Canada needs a legislative framework that is sufficiently flexible and forward-looking to address the regulatory issues associated with new inventions derived from biotechnology.[34] The federal government recently launched public consultations on the renewal of health protection legislation.

- *Intellectual property (IP) protection*: IP protection is important to the development and commercialization of biotechnology products. Inadequate patent protection causes market uncertainty, likely resulting in an outflow of funds and expertise. A number of key issues remain to be resolved, such as the treatment of higher life forms. The patent is the most common form of IP protection sought for inventions resulting from biotechnological research. Although hundreds of applications have been filed thus far, the Supreme Court of Canada has determined in December 2002 that higher life forms, i.e. plants, seeds and non-human animals, are not included in the definition of invention in the *Patent Act* and therefore are currently not patentable in this country. This distinguishes Canada from all G7 countries and, in fact, from the vast majority of OECD countries where patenting of higher life forms is permitted.[35] However, it should be noted that in May 2004, in a 5-4 decision, the Supreme Court ruled that if there is a patent on a gene or a cell in a plant, anyone using seeds or plants containing those genes or cells without permission is infringing on the patent.

- *Orphan drugs legislation*: Firms are more reluctant to invest in the research and commercialization of drugs that target medical conditions that afflict only a small percentage of the population. The U.S., EU, Australia and Japan have enacted legislation and implemented programs to address this market shortfall in order to stimulate innovation and

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[33] *Assisted Human Reproduction Act*, S.C. 2004, c.2 (Bill C-6)

[34] In its 2002 Speech from the Throne, the Government of Canada committed to renew federal health protection legislation to better address emerging risks, adapt to modern technology and emphasize prevention.

[35] In June 2002, the CBAC recommended that higher life forms that meet the required criteria be patentable, provided that certain safeguards were introduced at the same time. In December 2002, the Supreme Court of Canada ruled that the *Patent Act* does not clearly indicate that higher life forms are patentable; Parliament should therefore determine whether or not they should be. Either way, the *Patent Act* is currently ill equipped to deal with issues related to complex higher life forms. Industry Canada and other departments continue to analyze the issue.

> increase the safe availability of these so-called orphan drugs to their citizens. Canada allows access to drugs that are not otherwise available in this country under specific regulations and policies[36] but there is no Canadian orphan drug policy or legislation. Orphan drug policies typically grant market exclusivity and tax credits to manufacturers as incentives. Complete drug reviews are also conducted on orphan drugs before they can be marketed. With the recent developments in pharmacogenomics, and the resulting ability to target treatments for sub-groups of the population, it may be timely to consider implementing a legislative framework to facilitate access to these drugs.

The Committee is of the view that, given the rapid evolution of biotechnology, legislation must also be regularly reviewed once it has been enacted to ensure its continued appropriateness. This must be done in a proactive, systematic and timely manner to avoid reviews taking place in times of crisis.

Recommendation 48: The federal government should identify, prioritize and address legislative gaps impacting biotechnology. As a first step, it should accelerate the renewal of health protection legislation. To ensure legislation also continues to be appropriate, it should be monitored via regularly scheduled reviews that are provided for in legislation or in departmental mandates. When appropriate, independent scientific advice and public input should be sought in these reviews.

International Cooperation

In the Committee's view, smart biotechnology regulation involves using international regulatory cooperation more strategically, as stated in the previous section of this document. The same principles set out in Part I, Section 3.1 "International Regulatory Cooperation" can apply to products and processes derived from biotechnology. Canada could work with other countries on common or shared approaches to assessments, approvals and post-market reviews of biotechnology products in a systematic and consistent manner across departments.

The Committee further thinks that there are some areas of biotechnology in which Canada should take a leadership role internationally. In this fast-paced environment, Canadian inventions derived from biotechnology can sometimes precede the development of an international legislative framework. In such cases, and where these developments could give Canada a comparative advantage in developing or commercializing a biotechnology-derived product, Canada should take the lead internationally in developing biotechnology regulation.

Recent experience in food biotechnology shows how the federal government played a leadership role internationally both in setting standards and working to achieve international harmonization (see sidebar).

Recommendation 49: The federal government should be actively and strategically involved in international regulatory cooperation activities impacting biotechnology. It should encourage international and domestic experts to participate in independent peer reviews of studies, risk assessments and regulatory analysis. It should also identify instances where it is in Canada's interest to be a regulatory leader and actively pursue this objective.

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[36] The Notice of Compliance with Conditions policy allows manufacturers to market products before the end of clinical trials subject to certain conditions. The Special Access Programme – Drugs also exempts drugs from regulation by allowing practitioners to request access on a compassionate or emergency basis to drugs that are not sold in Canada. Authorization under the Special Access Programme does not guarantee that a drug is safe, efficacious or of high quality.

Positioning Canadian Regulations Internationally – The Food Biotechnology Experience

Agriculture and food is an important and innovative sector of Canada's economy. In the area of food crop biotechnology, government, academic and industry innovation has created an enviable capacity in new product development. Given that the benefits of innovation can be realized only when an appropriate regulatory stewardship process is available to provide timely access to markets, it is clearly in Canada's interest to pursue a sound regulatory framework for food biotechnology. Beyond the relevance of domestic regulatory stewardship, the importance of Canada's agricultural and food exports argue for developing and leveraging a leadership role internationally to improve Canadian influence in achieving international harmonization of regulatory standards that appropriately ensure consumer protection while providing a consistent, predictable and evidence-based regulatory environment internationally.

That is why Health Canada has decided to play a leadership role in Codex Alimentarius (the international standard-setting body for food) to develop practical guidance and international standards for the safety assessment of foods derived through biotechnology. From the start, Health Canada leveraged its internal expertise internationally by routinely participating in expert international consultations. Canadian guidelines were among the first comprehensive scientific assessment approaches to be published. Canada's experience and expertise in the assessment of genetically modified plants provided a practical demonstration of the effectiveness of the emerging scientific principles. The Canadian approach was therefore well positioned to act as the template for the development of an international standard, which was adopted by Codex in 2003 and now provides the basis for international harmonization of the regulatory requirements regarding food safety.

Information on Biotechnology and Citizen Engagement

There is an obvious need for appropriate legislation. But there is also a need to provide the public, industry and other regulators with understandable explanations and information. Recent surveys[37] confirm that only 16% of Canadians consider themselves to be very familiar with biotechnology. This lack of understanding can have a negative impact on the public's acceptance of products, even if these products have been properly evaluated for inherent risks. It also limits the public's grasp of Canada's international actions on specific biotechnology issues, including genetically modified organisms (GMOs). Further, firms — especially smaller firms and start-ups — also need access to clear regulatory information. Finally, federal biotechnology regulators would benefit from an up-to-date and accessible source of information on this broad topic.

While there is some information available from federal sources, there is no comprehensive, user-friendly, up-to-date source of information on regulatory developments in biotechnology. It is the Committee's view that the government must better inform all stakeholders. This would provide citizens with a stronger basis for informed involvement and improve the transparency of the legislative process. It would also assist Canadian biotechnology firms that are seeking to market new products and processes. It should be noted that a one-window consumer information centre was also recommended by the Canadian Biotechnology Advisory Committee in its August 2002 report, *Improving the Regulation of Genetically Modified and Other Novel Foods and Feeds*. As of August 2004, the federal government had not formally responded to the report.

The U.K. has devised a novel approach to informing biotechnologists and "enquiring minds from all walks of life": the Biotechnology Regulatory Atlas.[38] It is an effective retrieval system which signposts laws and official guidance as well as explanations and commentaries on biotechnology issues. It outlines both overarching and sectoral regulation requirements, including what firms need to do to comply with the law (e.g. preparing risk assessments, record keeping, notifying the authorities and obtaining licences). The Atlas provides all stakeholders with information on legislative trends, current debates and the international outlook. It also includes information on a variety of themes such as strategy and society, intellectual property, safety and welfare, contained use of GMOs, human genetics and therapy, and food and agriculture.

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[37] Public opinion research into biotechnology issues. Earnscliffe/Pollara, December 2003.

[38] See http://plus.i-bio.gov.uk/ibioatlas/.

In addition to providing relevant, accessible and up-to-date information, the federal government should ensure that there are opportunities for it to communicate with citizens, industry and provincial and territorial governments and develop a better understanding of each other's perspectives. In light of its significant ethical, social, environmental and economic implications, biotechnology is an area where government should be particularly active in engaging citizens and stakeholders and in encouraging public debate.

Recommendation 50: The federal government should implement an enhanced communications strategy which would include an accessible Web-based consumer and industry information service similar to the U.K.'s Biotechnology Regulatory Atlas and effectively inform target audiences of its existence and benefits.

Recommendation 51: The federal government should devise and implement a thorough and sophisticated approach to engage citizens and other stakeholders on public policy issues involving biotechnology. This should include the sharing of information on current scientific evidence and risk management analysis. ◆

1.3 Enabling First Nations Economic Development

More and more First Nations communities are promoting economic development and looking to manage their own lands and resources. Today there are mining, forestry, oil and gas, aquaculture and other business developments under way on reserve lands across Canada. The goal behind these activities is to build stronger indigenous economies, leading to greater economic independence for First Nations.

The regulatory regime on reserves, however, is undermining this agenda. The current regime is complex and poorly defined. The majority of regulations are based on an Act that was brought into force in 1876 and underwent its last major update in 1951 — the *Indian Act*. Efforts are being made to correct this situation but, in the Committee's view, they are moving far too slowly. The Committee notes that many of these same issues were raised in the 1996 report by the Royal Commission on Aboriginal Peoples. The government must move quickly to establish a modern, efficient regulatory regime that supports development and creates a healthier environment for business and investment on reserves. Consistent with the Committee's vision statement, a key element of the new regime should be strengthened cooperation between First Nations, governments and industry.

Indigenous economies today are contributing increasingly to provincial, regional and national economies. Over the last decade, there has been a noticeable rise in independent business development and joint ventures with large Canadian and international firms. For example, First Nations are participating in major industrial initiatives, particularly in the natural resources sector, where there is significant expansion in oil and gas, hydro-electricity, forestry and mining. To ensure that they can fully benefit from these projects, and to support the projects' success, First Nations must have effective regulatory arrangements in place, including capacity-building measures. (Issues specific to major industrial developments are discussed in more detail later in Part II.)

Aboriginal Entrepreneurs in Canada

Aboriginal entrepreneurship represents an increasingly dynamic segment of the Canadian economy. Self-employment among Aboriginal people continues to be on the rise. According to the 2001 Census, growth in self-employment for the Aboriginal population was 10 times that of the non-Aboriginal population between 1996 and 2001.

There are important benefits for Canada in First Nations economic development. It provides employment, helps build more diverse skills sets on reserves, creates wealth and can help reduce demands on the social safety net. Economic development is key to improving the quality of life for Aboriginal citizens and advancing their participation in the Canadian economy.

1.3.1 Regulatory Arrangements and Key Challenges

Given its limited timeframe and resources, the Committee was unable to address all Aboriginal-specific regulatory issues. The focus of this section is the regulatory regime for First Nations communities located south of the 60th parallel, particularly with respect to land and resource management issues.

Regulatory arrangements for First Nations lands and resources vary according to location and jurisdiction. In the North, resource management falls under a legislative framework that applies to all northerners, including Aboriginal and non-Aboriginal residents. Other variances exist as a result of comprehensive land claims or self-government agreements that have been settled (which confer regulatory authority on First Nations in some areas). Some of the regulatory issues in the North are addressed later under Section 1.5 "Oil and Gas Exploration and Development."

Land and resource management in southern communities is guided primarily by the *Indian Act* and the *Indian Oil and Gas Act*, both of which fall under the responsibility of the Department of Indian Affairs and Northern Development (DIAND). Five southern groups have achieved comprehensive or sectoral self-government status. But the majority of communities are subject to federal regulations administered by DIAND and other federal departments.

The Committee considered three key regulatory challenges related to southern First Nations economic development:

- updating legislative and regulatory arrangements;
- building regulatory management capacity; and
- reducing regulatory complexity and burden.

Updating Legislative and Regulatory Arrangements

The *Indian Act* is widely considered to be outdated and limited in its coverage of economic development activity. The approval process for development projects, as set out in the regulations to the Act, is cumbersome and lengthy. Projects can take years to approve, resulting in the loss of opportunities, jobs and the potential for economic growth.

The *First Nations Land Management Act* (FNLMA) was passed in 1999 to address the deficiencies of the *Indian Act* related to land and resource management. The FNLMA gives signatory First Nations the freedom and responsibility to manage their own reserve lands, natural resources and revenues. It allows them, for example, to develop their own land codes and pass and enforce laws, including regulations.

The creation of the FNLMA was an important step in enabling economic development. However, progress is slow. In passing this legislation, Parliament indicated that implementation should be limited initially to a small group of bands to ensure an orderly and effective process. Currently, 12 out of 629 communities are operating under the FNLMA, 24 are in the development process and 52 are awaiting entry. The vast majority of bands are still subject to the regulations under the *Indian Act* and, at the current rate, it will be years before they can be considered for coverage under the FNLMA. The Committee believes that aggressive action is needed to rectify this situation. The federal government should reconsider its approach; it should accelerate the current process to ensure that all bands have the benefit of a more timely and effective regulatory process, consistent with a Smart Regulation approach.

In addition, there are significant gaps in regulation on reserves which contribute to regulatory uncertainty and can discourage investment. First Nations that want to develop commercial and industrial projects on reserve land are prevented from moving major projects forward because the required regulations are lacking (e.g. health and safety, environmental protection and enforcement regulations). Current federal legislation does not cover or provide regulations for projects of this type. And provincial regulation — which governs most other business and commercial development in Canada — does not apply on reserve lands. This situation is a result of the division of responsibility for First Nations, as set out in the Constitution. DIAND is exploring options to address this situation, including the possibility of incorporating provincial regulations by reference.

> **Recommendation 52: The federal government must move quickly to create an efficient, more responsive regulatory environment in First Nations communities, thereby enabling them to realize full economic growth. A key element in designing a successful approach should be to improve cooperative arrangements between First Nations, governments and industry.**

Recommendation 53: Working with First Nations, the federal government should accelerate its agenda to introduce new legislation or amend existing legislation as necessary, so that bands have the benefit of a modern regulatory regime in the shortest possible time. In addition, the federal government should move immediately to address regulatory gaps that inhibit the development of commercial and industrial projects on reserve.

Reducing Regulatory Complexity and Burden

In addition to DIAND, there are several other federal departments and agencies with regulatory responsibilities that affect First Nations communities, including Fisheries and Oceans Canada, Environment Canada, Natural Resources Canada, the Canadian Environmental Assessment Agency, Health Canada and Human Resources and Skills Development Canada. The result is a complex web of regulations and management regimes, and a heavy burden on First Nations communities, approximately half of which number fewer than 500 people. Certain provincial and territorial regulations, such as those of general application, also apply to First Nations.

The full scope and nature of regulatory activity in communities is unknown at present, as there is no process or federal mechanism to collect this information or coordinate regulatory activity. This is a fundamental issue in developing a Smart Regulation regime. The federal government should ensure that regulations on reserves are appropriate, coordinated and not overly burdensome to communities. As part of this effort, due consideration should be given to First Nations in developing or amending and enforcing key federal legislation (e.g. the *Canadian Environmental Protection Act, 1999*; *Species at Risk Act*). In addition, the government should maximize the contribution of advisory bodies such as the National Aboriginal Economic Development Board. The Committee notes that ensuring well-coordinated regulatory arrangements for communities and eliminating duplication will become increasingly important over time, as more First Nations achieve self-government status.

Recommendation 54: The federal government should review the full scope of regulatory activity in First Nations communities with a view to reducing the regulatory and administrative burden placed on them. Outdated or duplicative regulations should be eliminated and regulatory gaps addressed. In support of this initiative, the government should put in place a centralized process or mechanism to ensure better coordination and monitoring of regulatory activity in communities.

Building Regulatory Management Capacity

How bands execute and operationalize regulations is also important. Initiatives are under way within DIAND to strengthen the land and resource competencies and professional skills base in First Nations communities and governments. The Committee believes this is a critical success factor in developing Smart Regulation in communities.

A few organizations and institutions are in place now that give First Nations the authority to regulate in key areas or give them a leadership role working with DIAND. In addition, legislation is being developed within DIAND that would give First Nations additional responsibilities, including helping to build capacity on reserves. The existing Indian Resource Council, First Nations Lands Advisory Board, the National Aboriginal Land Management Association, and the Aboriginal Environmental Network could form the basis for more formalized arrangements that would provide for greater control and direction for First Nations and First Nations institutions.

Recommendation 55: The federal government should accelerate the development of initiatives to improve the skills and capacity of First Nations to make rules and manage regulations. As a key step, the government should give priority to developing the appropriate legislation that would help strengthen the professional skills base in First Nations communities. 🍁

1.4 The Environmental Assessment Process

Under the *Canadian Environmental Assessment Act* (CEAA), environmental assessment is a project planning tool used to help eliminate or reduce potential harm to the environment resulting from the issuance of a federal permit, when the federal government is a project proponent or when federal funding or land is involved. More broadly, assessments support efforts to achieve sustainable development.

The CEAA, which is administered by the Canadian Environment Assessment Agency,[39] provides for four types of environmental assessment: screening, comprehensive study, mediation and assessment by a review panel. The vast majority of projects (greater than 99% of all projects assessed) are assessed as screenings. The *Comprehensive Study List Regulations* under the CEAA identify those projects likely to result in significant environmental effects and thus require a comprehensive study assessment. The primary differences between screening reviews and comprehensive studies are the complexity and length of the process, and the extent of public consultations, which are greater for comprehensive studies. In terms of the time required, screenings generally take a few months, comprehensive studies require about a year and review panels may require over a year.

Public concern and the potential for significant adverse environmental effects tend to be the major factors in determining what type of environmental assessment is required. Regulators or other government decision makers must consider the extent to which both these factors warrant a more thorough assessment by a mediator or review panel. Regulators have the authority to ensure that projects with issues of significant public concern are subjected to a review panel or other public consultation.

Federal environmental assessments are generally meant to result in the identification of measures to mitigate potentially adverse environmental consequences rather than cause the cancellation of a project. Rather than being strictly a planning tool, however, the Committee has heard that industry and citizens perceive environmental assessments as de facto project approval tools for the federal government.

Both federal and provincial governments have responsibilities for environmental assessment. The specific responsibilities overlap and also vary considerably. For example, provinces are responsible for natural resource projects within their borders, while the federal government is responsible for projects in various areas such as those that affect fish habitat and navigable waters, or that have significant adverse effects that cross interprovincial or international borders. The use of environmental assessments can also vary among jurisdictions. For example, Saskatchewan uses the environmental assessment process not only as a planning tool, but explicitly as part of its development planning/project approval process.

1.4.1 Key Challenges

The Committee recognizes that the federal environmental assessment legislation was just revised in 2003 following extensive consultation and that there is not enough evidence yet to assess how well the revisions address environmental assessment issues (see the sidebar on the *Canadian Environmental Assessment Act*). Accordingly, the Agency should fast-track implementation of the new legislation. It should be noted, however, that the recent amendments to the CEAA left some issues untouched where there was not consensus on how to proceed (e.g. enforcement mechanisms, the principle of self-assessment, etc.).

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[39] While one of the Agency's functions is to administer the CEAA, it does not carry out environmental assessments.

Revisions to the *Canadian Environmental Assessment Act* (2003)

Bill C-9 made the following revisions to the CEAA:

- creation of a federal environmental assessment coordinator role;
- mandate to establish a Quality Assurance Program to examine federal assessments;
- requirement to create an Internet database of all federal environmental assessments;
- mandatory follow-up programs for specified projects;
- tools to deal efficiently with projects that have inconsequential effects;
- a more certain comprehensive study process;
- more opportunities for public participation in the comprehensive study process supported by participant funding; and
- use of regional environmental studies.

Further regulatory and policy changes are under way to complement these legislative amendments. They include:

- a government-wide commitment to address the problem of departmental environmental assessment processes not commencing until well into project planning ("late triggering") by implementation of a system whereby a department would be "automatically in" from the project outset;
- additions to the *Exclusion List Regulations* to exempt projects known to have insignificant effects; and
- revisions to the *Federal Coordination Regulations* to reflect the new federal environmental assessment coordinator role in the Act.

The amendments to the CEAA resulted from a multistakeholder consultation. The following examples illustrate how the changes address some of the concerns identified by different parties:

- Environmental non-governmental organization and community concerns were addressed through increased transparency (e.g. creation of an Internet registry) and consultation requirements.
- Government concerns about assessing too many small projects were addressed through additions to expand the *Exclusion List Regulations* and to provide a new class for screenings.
- Many industry and provincial concerns about efficiency and predictability were addressed through the federal environmental assessment coordinator provisions and a more certain comprehensive study process.

Moreover, the environmental assessment process is one of the issues about which the Committee heard the most complaints and it was viewed as a key priority for regulatory reform by many industry and environmental non-governmental organizations, given its impact on environmental management and on numerous economic sectors across Canada. The Committee also heard scepticism over whether the recent changes to the CEAA would make the environmental assessment process much more effective or, in some cases, even more cumbersome.

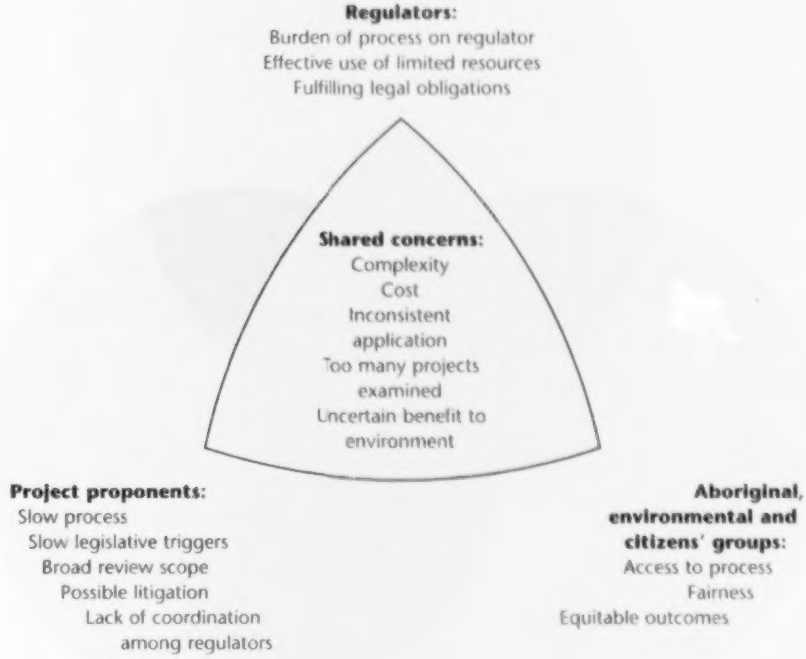
The Committee heard a high degree of frustration from industry, which views environmental assessment as important, but finds the process slow, lacking in clarity, costly and occasionally of uncertain benefit to the environment. Provincial governments also question the slowness of federal environmental assessment processes and their overlap with provincial/territorial regulations. Many provinces also view the federal role as an intrusion on provincial/territorial jurisdiction. Virtually all parties agree that, as a whole, environmental assessment processes are overly complicated.

Environmental non-governmental organizations sometimes argue that environmental assessments are mere window dressing for decisions already made. At the same time, some government officials question allocating scarce resources to assessing small or routine projects whose effects and contributions to advancing environmental priorities are well understood.

Finally, the environmental assessment process can represent the only, or at least an easily accessible, route for citizens to have a direct voice in development proposals. Interested citizens often view this process as unfair since they have limited financial and legal resources to participate. In particular, local communities impacted by a project can feel that they do not have the opportunity to provide input and believe that their interests are not always reflected in the final regulatory decision. In addition, the purpose of environmental assessments is not always well understood, particularly by citizens, who may expect the results of an environmental assessment to end or significantly alter a project. When this does not occur, they feel a sense of frustration and powerlessness. In addition, citizens sometimes perceive the government as a proponent or a major supporter of a project.

While all of these parties have specific views, the following diagram shows that there are some common elements to their concerns.

Concerns Expressed About the Canadian Environmental Assessment Process


Regulators:
Burden of process on regulator
Effective use of limited resources
Fulfilling legal obligations
Shared concerns:
Complexity
Cost
Inconsistent application
Too many projects examined
Uncertain benefit to environment
Project proponents:
Slow process
Slow legislative triggers
Broad review scope
Possible litigation
Lack of coordination among regulators
Aboriginal, environmental and citizens' groups:
Access to process
Fairness
Equitable outcomes

1.4.2 An Integrated Approach to Environmental Assessment

One of the most consistent concerns expressed to the Committee about the environmental assessment process was the lack of effective coordination — both within the federal government and among orders of government.

Coordination Between Federal Departments

When federal environmental assessment legislation was first created, the responsibility for environmental assessments was appended to departments' existing activities. As a result, project proponents and stakeholders may have to interact with many departments at the same time. This feature contributes to the complexity of the environmental assessment process and the lack of consistency of environmental assessment requirements. That said, this approach, referred to as "self-assessment," has the benefit that the responsible department is usually well positioned to understand the intricacies of a proposed project and the ways that adverse environmental effects can be mitigated. This process contrasts with the typical approach of provinces, where one agency leads environmental assessments.

At the same time, several stakeholders have raised the issue of environmental assessment procedures being applied unevenly within departments at the regional level. Specifically, the same regulation can be inconsistently interpreted and applied, resulting in similar types of projects receiving markedly different treatment from regional office to regional office within the same federal department.

Coordination Among Federal, Provincial and Territorial Governments

Projects can fall under the jurisdiction of federal and provincial/territorial governments, triggering review by both. The Committee heard that the current framework of overlapping and duplicative environmental assessment processes between orders of government had to be improved. Involving various orders of government in the same project does not necessarily lead to the environmental sustainability of the project. Moreover, this intergovernmental overlap seems to reflect a lack of trust among federal-provincial-territorial governments and an unwarranted preoccupation with jurisdiction, which does not serve the public interest. As identified in Part I, Section 3.2 "Federal-Provincial-Territorial Regulatory Cooperation," Canadians are expecting governments to work together to deliver high standards of protection and service.

One means of improving the coordination of multi-jurisdictional environmental assessments has been provided by the Sub-agreement on Environmental Assessment under the Canada-Wide Accord on Environmental Harmonization. It promotes the effective application of environmental assessment when two or more governments are required by their respective laws to assess the same proposed project. It includes provisions for shared principles, common information elements, a defined series of assessment stages and a single assessment and public hearing process.[40]

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[40] The Sub-agreement is implemented through bilateral agreements between the federal government and individual provinces and territories. To date, bilateral agreements have been signed with British Columbia, Alberta, Saskatchewan, Manitoba, Quebec and the Yukon Territory. Negotiations are under way with Nova Scotia and Newfoundland and Labrador, while a draft agreement with Ontario was under development during the preparation of this report. Where bilateral agreements are not in place, project-specific arrangements have been used to prevent duplication.

Despite encouraging signs of progress in the federal-provincial coordination of environmental assessments (e.g. the joint review of two recent oil sands projects by the federal government and the Alberta Energy and Utilities Board), the Committee heard from industry representatives, particularly those in the oil and gas and electricity-generation industries, that problems remain in coordinating timing, information requirements and public participation. For example, one province expressed concern that it was difficult, and sometimes impossible, for the federal government to recognize data collected through previously conducted provincial assessments and to use it in federal assessments.

A New Approach

The coordination challenge and other issues related to environmental assessments could be improved by accelerating implementation of the CEAA amendments and by taking steps to improve coordination within the federal government and with provincial and territorial governments. However, the Committee feels that this would take considerable time and effort to implement and it would only marginally improve the situation.

If the environmental assessment process is not meaningfully improved, the Committee is concerned that the credibility of the assessment process will continue to erode and its effective use will be jeopardized. Therefore, it believes that environmental assessment is an area where it is time to move beyond harmonization and towards a single, nationally integrated approach encompassing federal, provincial and territorial processes. This idea was generally supported by both industry representatives and non-governmental organizations during our consultations. The Committee advocates a national environmental assessment system that is:

- coordinated, both within the federal government and between the different jurisdictions;
- results-based;
- timely and predictable;
- cost-effective; and
- accessible.

More specifically:

- There should be one set of documents prepared per project, which would be used by all the government organizations involved, whether they are federal or provincial.
- When necessary, there should be one hearing, one time, per project.
- Results should be monitored to demonstrate that environmental assessments lead to appropriate environmental protection.
- Timelines should be set at the outset of the project for the different steps in the environmental assessment process and these timelines should be respected.
- All triggers for assessment should be identified from the outset in order to allow for concurrent — if not single — processes to take place.
- All stakeholders (e.g. citizens, non-governmental organizations and Aboriginal peoples) should have a fair opportunity to present their views.
- Multiple assessments on a single project should be conducted concurrently.

This approach would be desirable from the standpoint of clarifying and streamlining the process, conducting a more holistic assessment of a project and enabling the development of expertise in this area, while ensuring environmental protection and promoting economic development. This approach could also improve the consideration of cumulative impacts of several projects on a single ecosystem and ensure that the environmental assessment process adapts to new scientific advances and changing circumstances. One potential means of achieving this vision could be the creation of a single national environmental assessment agency in which the federal, provincial and territorial governments would be equal partners.

The Committee recognizes that such an undertaking would require significant legal and political considerations to be addressed, but feels that the time is right for the federal government to take a leadership role in initiating discussions with the provinces and territories on how to develop and implement this national approach.

> **Recommendation 56: The federal government should begin discussions with the provincial and territorial governments to develop a nationally integrated environmental assessment process for Canada in which the different jurisdictions would collaborate as partners.**

1.4.3 Other Issues

In addition to the previous analysis, the Committee has also put forth a number of other suggestions on how to improve the environmental assessment process in Canada. The following recommendations may be implemented as part of the proposed national environmental assessment approach or as stand-alone initiatives.

A Single Federal Agency

In the absence of an agreement to establish a national approach to environmental assessment, priority must be given to improving coordination efforts within the federal government and among orders of government. As a first step, the federal government should accelerate the amendments to the CEAA. In addition, the government should establish a single federal agency responsible for carrying out environmental assessments under federal jurisdiction. As a single window for the federal government on environmental assessments, this agency would provide a more effective and simpler process for project proponents and other interested parties. It would also better support the development of expertise within the federal government in this area. A single federal agency would also be better positioned to work with multiple jurisdictions (e.g. provincial/territorial governments) and stakeholders (e.g. Aboriginal peoples, citizens and conservation groups) to deliver high-quality assessments that reflect the public interest in a timely manner.

> **Recommendation 57: The federal government should create a single environmental assessment agency in order to carry out assessments under federal jurisdiction and collaborate with other orders of government.**

At the same time, the federal government should work closely with the provinces and territories to improve the operation of current cooperative environmental assessment agreements in order to ensure that the assessments are seamless and incorporate aspects such as single project proposals based on harmonized information gathering and reporting, the use of shared data, single hearings and common timelines. In the context of these improvements to current cooperative processes, the federal government should consider focusing its efforts on large projects (e.g. projects which take place in more than one jurisdiction) and on those with potentially greater risks to the environment.

Concurrent Processes

In addition to having many departments involved in environmental assessments, some departments' requirements are not triggered at the outset of the environmental assessment process, leading to sequential assessments on a single project. This situation adds to the uncertainty of the business environment and delays decisions by regulators, without necessarily adding benefits to the protection of the environment.

For example, this has been raised as a major issue, particularly by the offshore oil and gas industry, in the context of administering the *Fisheries Act*. In order to address these concerns, Fisheries and Oceans Canada is taking steps to implement an "automatically in" approach whereby the *Fisheries Act* review would take place at the same time as other required environmental assessments. This approach would be taken in the case of large projects that would very likely cause the triggering of an assessment under the *Fisheries Act*.

The government should take steps to ensure that when more than one environmental assessment is required by federal departments, they are conducted concurrently and not sequentially, while maintaining the high quality and analytical rigour of the process. The Committee feels that improving coordination and integration in this area could lead to some significant efficiencies. Moreover, such a concurrent approach could extend to the entire regulatory process, whereby the regulatory approval mechanisms can be launched even before the environmental assessment has been completed.

> **Recommendation 58: Multiple environmental assessments on the same project conducted by different authorities should be conducted concurrently, not sequentially.**

Substitution

The CEAA has always included a provision for the Minister of the Environment to allow the public hearing process of another federal authority to be used as a substitute for a review panel. This could help to reduce the administrative complexity of environmental assessment in cases where public participation is required. The Act allows this substitution where the Minister is satisfied that the substituted process meets the conditions specified under the CEAA, including those for public participation.

Substitution would give the substitute authority greater control over the project design and the broader regulatory approval process. For example, the National Energy Board would conduct an approval review for a proposed pipeline as well as the environmental assessment. Review processes could be made more efficient and timely without reducing the quality of the environmental assessment or compromising the public's ability to participate. The applicant and other interested parties would receive clearer communication and would be more certain of the entire regulatory review process, including the environmental assessment component.

Many stakeholders cited the use of substitute authorities as a means of helping to streamline this process. To date, however, substitution has never been granted due to technical issues such as arrangements for participant funding for consultations. In most cases, these issues could be resolved through an administrative arrangement.

Recommendation 59: The Canadian Environmental Assessment Agency and potential substitute authorities, such as the National Energy Board, should negotiate an agreement to enable substitution when an environmental assessment by a review panel and other project approval processes are both required.

Monitoring and Evaluating Results

The Committee heard that the benefits of environmental assessment to the ecosystem are generally assumed but rarely measured. Industry representatives are frustrated that there are few effective tools to determine whether the mitigation measures they have been asked to undertake by a regulator actually help the environment. Environmental groups are equally concerned about the inability of government agencies to evaluate a project's environmental impact and to enforce compliance with the results of the assessment. This situation, combined with a procedure that is perceived as unduly complex, has started to affect the legitimacy of the environmental assessment process.

The contribution of environmental assessments to protecting natural ecosystems and improving the sustainability of projects must become more measurable and transparent to project proponents, affected communities and other stakeholders. The Committee recognizes that it can be difficult to attribute post-project changes in the environment to a specific project, particularly with species subject to natural cycles in their population levels. However, methods must be developed to show that the mitigation measures taken by proponents, as a consequence of the environmental assessment process, do produce results.

To ensure that environmental protection objectives have been achieved, the recent CEAA amendments provide for follow-up programs, which are defined as programs for verifying the accuracy of the predictions of environmental effects and determining the effectiveness of any mitigation measures against specified indicators. The Quality Assurance Program being designed and implemented by the Canadian Environmental Assessment Agency will also serve to confirm results. Lastly, building on recommendations of the National Roundtable on the Environment and the Economy, the federal government plans to incorporate key indicators on clean water, clean air and emissions reduction into its decision making.

Departments are required to consider whether a follow-up program is warranted for screening assessments and, if so, they must design and implement such a program. Follow-up programs are also mandatory for projects that are subject to a comprehensive study, mediation or assessment by a review panel. The Agency will be establishing an electronic repository for follow-up results to share information and act as a clearinghouse for best practices. It should be noted that at least one department has expressed a reservation about participating in the repository due to workload.

Recommendation 60: Specific targets, performance measures and indicators for monitoring a project's environmental impacts and the effectiveness of mitigation measures should be considered essential elements of environmental assessments. This approach would incorporate lessons learned from past assessments, post-approval audits and reports on monitoring. These elements need to be developed in consultation with the provinces, territories and other regulators, particularly if a national environmental assessment process is eventually established.

Enhancing the Use of Strategic Environmental Assessments

As discussed earlier, the environmental assessment process is viewed by many interveners as the most effective means of accessing decision makers on a given project. However, the Committee often heard that the consultation process for many assessments has become bogged down in discussions over broader public policy issues (e.g. whether to drill for oil and gas off Canada's Atlantic coast at all), rather than focusing on the environmental viability of a specific project (e.g. studying the impact of a specific drill-site, the use of seismic testing in a specific section of the Atlantic coast, etc.). These broader public policy debates not only divert attention from the specific project at hand, but further add to the time delays inherent in many environmental assessments.

One means of addressing this concern is the use of strategic environmental assessments. The strategic environmental assessment of a government policy, program or planning proposal is required when such an initiative requires a Cabinet decision and when the implementation of a project may result in important environmental effects, whether they be positive or negative. This process enables environmental issues to be considered more fully in the development of public policies. The Commissioner of the Environment and Sustainable Development is currently auditing the implementation of this process.

Strategic environmental assessments present an opportunity to examine proposed federal policies and programs in a manner that is transparent and supports effective, focused environmental assessments for specific projects. The Committee considers that the government could enhance the use of this process if it were to conduct these assessments before considering development projects and before significant capital is invested. Strategic environmental assessments would enable interested parties, such as Aboriginal representatives and local communities, to intervene early in the process to address public policy decisions and would help to create an atmosphere of regulatory certainty for industry when it subsequently comes forward with specific project proposals. Following the strategic environmental assessment, industry could proceed with the project without further revisiting public policy decisions, subject to the subsequent requirements of the CEAA and regulatory compliance with technical matters.

In the case of offshore waters, the use of strategic environmental assessments could directly contribute to the development of plans to guide the location and intensity of all marine activities, thereby increasing operational security and environmental protection. In the specific example of reviewing offshore oil and gas development, conducting a strategic environmental assessment would allow subsequent exploratory and development activities to be assessed solely on technical grounds without revisiting the issue of whether the industry should operate in this area or not. If the assessment were done before the government released parcels for development, it would identify the conditions and mitigation measures that project proponents would be expected to take. Subsequently, this process could also enable the use of screening assessments rather than comprehensive assessments, which require more resources and time.

Because provincial and territorial governments have responsibility for broad land use planning and resource management, they should be involved in these strategic environmental assessments.

> **Recommendation 61: The government should conduct public strategic environmental assessments to provide people with an opportunity to discuss overall development issues in the offshore regions or on federal lands, or issues related to a potential new federal policy or policy change.**

The Fisheries Act

The *Fisheries Act* represents a significant trigger for an environmental assessment when a project could damage fish habitats. Many of the greatest irritants cited by stakeholders were related to the *Fisheries Act* and its administration and enforcement by Fisheries and Oceans Canada. In some regions, this sentiment has been compounded by the use of armed fisheries officers monitoring freshwater locations. The major concerns related to environmental assessments conducted through the *Fisheries Act* include:

- a lack of clarity and transparency in the definition of some terms contained in the legislation (e.g. "harmful alteration, disruption or destruction" in the *Fisheries Act* and "significant adverse environmental effect" in the CEAA);
- imprecision as to which activities and practices are considered harmful and which are the acceptable mitigation measures under the *Fisheries Act*;
- identification of the need for an environmental assessment under the *Fisheries Act* late in the process, leading to sequential assessments; and
- the often inconsistent interpretation and enforcement of regulations between regions or sometimes within a region, lack of predictability and lack of transparency, which can lead to decisions by regulatory officers which are perceived as capricious and abusive.

Given these concerns, it is therefore more difficult for project proponents to plan a project and be certain that it meets regulatory requirements.

In particular, these challenges hamper hydroelectric generation and transmission projects, which are also often affected by the need for coordination between federal and provincial authorities. However, the Canadian Electricity Association and Fisheries and Oceans Canada have developed an MOU which shows real promise as a means of achieving mutual understanding and ensuring clarity, consistency and coherence in the implementation of federal environmental laws and regulations. In addition, Fisheries and Oceans Canada has developed a plan to resolve these issues, as explained in the sidebar.

> **Recommendation 62: Fisheries and Oceans Canada should accelerate its implementation of planned improvements to its fish habitat system and related involvement in environmental assessment.**

Risk Management

The scope and complexity of environmental assessments should reflect the nature and inherent risk of a project. Accordingly, risk management principles should be used to focus the government's efforts on assessing projects with potentially greater risk to the environment while taking into account impacts of small projects that can generate greater risks. The *Exclusion List Regulations* under the CEAA have been reviewed and will be expanded so that many small projects that are known to have insignificant environmental effects will be exempted from the requirement for an assessment. This measure and the new use of class screening reports are expected to reduce the number of environmental assessments by one-third.

In addition to this recent review, the *Comprehensive Study List Regulations* under the CEAA should be similarly reviewed to ensure their efficacy. The Committee notes that the CEAA gives the Minister of the Environment the power to approve changes to the *Comprehensive Study List Regulations* and it feels that the government's quick action to review these regulations could have significant impacts on regulatory efficiency and effectiveness.

Fisheries and Oceans Canada: Introducing Smart Regulation to the Habitat Management Program

Fisheries and Oceans Canada is responsible for seacoast and inland fisheries under the *Fisheries Act*. Within this context, the department's *Policy for the Management of Fish Habitat* provides a framework for the conservation, restoration and development of fish habitat through the principle of "no net loss" (NLL). The policy contains a mix of regulatory (protection and compliance) and non-regulatory strategies (proactive measures such as stewardship and partnering). The department receives between 10,000 to 12,000 project referrals annually for evaluation of their impact on fish habitat. Although there is no regulatory obligation for proponents to seek approvals, non-compliance with the *Fisheries Act* can lead to prosecution. Certain decisions under the *Fisheries Act* are triggers under the *Canadian Environmental Assessment Act*. As a result, a project requiring an authorization for impacts to fish habitat under the *Fisheries Act* triggers the need for an environmental assessment. In 2002–2003, approximately 950 environmental assessments were "triggered" under the *Fisheries Act* and the *Navigable Waters Protection Act* (NWPA) and were subject to review by Fisheries and Oceans staff (it should be noted that responsibility for the NWPA has subsequently been transferred to Transport Canada).

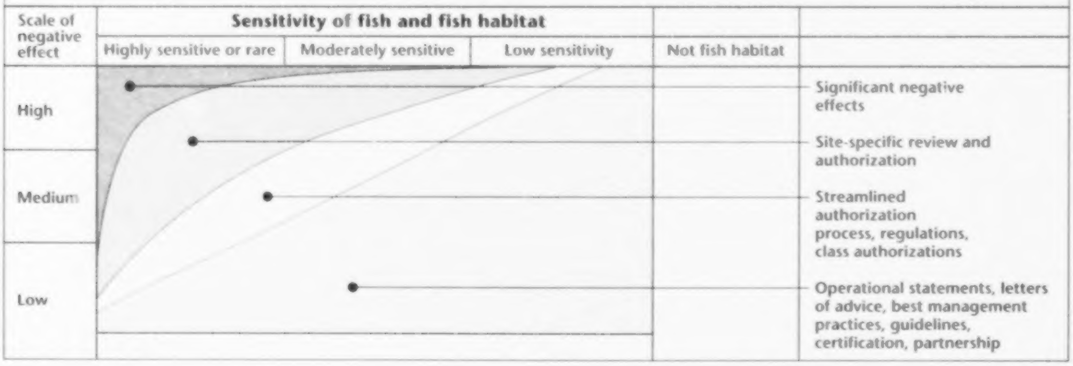
Industry, provincial and territorial governments, other federal departments and other stakeholders have expressed serious concern over the lack of clarity in the *Fisheries Act*, timely and consistent action by enforcement authorities, and the examination of projects with no apparent implications for fisheries.

In the context of its 2003 programs and expenditures review, the department initiated a review of the Habitat Management Program (HMP) in order to achieve a better balance between environmental and socio-economic considerations and increase the predictability and timeliness of decision making. A plan is now under way to modernize the HMP's environmental processes so that the program can focus resources on regulatory activities that provide the greatest value in reducing risks to fish habitat, reduce the burden on industry, and enable re-investment in innovative approaches to meet its mandate.

The review has determined that many project referrals received by the department are of low to medium risk. Of the thousands of referrals received annually, only 500–600 projects could result in harmful alteration, disruption or destruction (HADD) to fish habitat. The first and key component of the plan is the development of a Risk Management Framework to ensure efforts and resources target habitat priorities. The framework is integral to the department's modernization plan and consists of two elements which determine the appropriate level of risk. The first is a model used to determine the effects on fish habitat as a result of a given activity. The second is a risk matrix that incorporates the scale of negative effects and the sensitivity of the fish habitat in order to make a determination on risk category (see the chart below).

In addition, management tools will be developed to guide decision making based on level of risk and streamline the referral process. Medium- and low-risk projects are being categorized and tools and operating procedures are being developed to help proponents determine what action is needed. For example, for medium- to low-risk projects (such as those for agricultural drains), class authorizations are being used to reduce the burden on stakeholders and the number of assessments carried out by the department. For low-risk projects, about 20 fact sheets to help stakeholders proactively comply with the *Fisheries Act* will be released in 2004. Additional tools will be developed with industry and the provinces, and appropriate consultation measures are under consideration for First Nations and other stakeholders.

Consistent with a Smart Regulation approach, the department's goals are to increase the predictability and coherence of program delivery across the country by working more closely with other regulatory authorities (federal, provincial and territorial), and to strengthen partnerships with key stakeholders. In addition, a new management approach will better position the department to identify and review major projects to improve timeliness and consistency in decision making and to better harmonize reviews with other organizations. This will include a clearer separation between CEAA and *Fisheries Act* processes and early "triggering" of the CEAA on major projects.


Scale of negative effect
Sensitivity of fish and fish habitat
Highly sensitive or rare
Moderately sensitive
Low sensitivity
Not fish habitat
High
Medium
Low
Significant negative effects
Site-specific review and authorization
Streamlined authorization process, regulations, class authorizations
Operational statements, letters of advice, best management practices, guidelines, certification, partnership

Recommendation 63: The *Comprehensive Study List Regulations* should be evaluated to ensure that the greater complexity of the process (compared with screening) would result in improved environmental protection. Consideration should also be given to modifying the list of projects or altering thresholds where experience has demonstrated that a comprehensive study is warranted because there is a potential for significant adverse environmental effects.

Consultation

Public participation is a key element of the environmental assessment process. Communities that could be affected by projects need an opportunity to ask questions when significant issues arise or major new developments are proposed. As these groups often have limited resources, participant funding for comprehensive studies and review panels plays an important part in ensuring that such communities can contribute to the process.

Aboriginal traditional knowledge has been explicitly recognized in the CEAA and may be considered in conducting an environmental assessment. There is currently no guidance for responsible authorities on the consideration of this knowledge in environmental assessments.

Recommendation 64: Participant funding must be recognized as an essential element of environmental assessment to enable citizens to participate in the assessment process. Guidelines for participant funding should provide clear criteria as to who should receive participant funding in the environmental assessment process and for what purposes.

Recommendation 65: The federal government, in consultation with Aboriginal communities, should provide guidance on how Aboriginal traditional knowledge can be factored into an environmental assessment, while ensuring the balance necessary to maintain viable project timeframes. ♣

1.5 Oil and Gas Exploration and Development

The upstream (exploration and development) oil and gas industry is the single largest private investor in Canada, with capital investments of over $28 billion in Canada in 2003. The sector's companies were valued in revenues in excess of $75 billion in 2003 and are currently responsible for 500,000 jobs in Canada.[41] Canada currently ranks as the world's third largest natural gas producer and ninth largest oil producer. However, Canada's exploration and production costs for these resources are among the highest in the world.[42]

The conditions under which oil and gas companies are operating in Canada are changing. Reserves in western Canada are maturing and future exploration will increasingly be focused on relatively new developments — such as the Oil Sands, the North and the offshore — and new extraction innovations such as the coalbed methane production of natural gas. The structure of the industry is also changing as it is becoming increasingly integrated at the global level and Canada is competing with other foreign jurisdictions for investment capital to sustain the industry. Moreover, Canada's international obligations on climate change will have major implications for this and other industries, as well as for their customers in the future.

Concurrently, Aboriginal communities and non-governmental organizations have expressed concerns about these new developments, for example the potential impact of seismic testing, drilling and the construction of pipelines on environmentally sensitive areas such as Canada's North.

The Committee believes that regulation of the upstream oil and gas sector should allow for the development of this resource in Canada in a manner that respects the environment and is sustainable for future generations. At the same time, regulation must enable an economically competitive and innovative industry that contributes to Canadians' quality of life, and must ensure the development of a secure, reliable and safe supply of this resource for all Canadians.

This section of the report will focus on the so-called "frontier" sectors of development: the North and the offshore. It should be noted that only selected regulatory issues pertaining to oil and gas exploration and development will be discussed. Readers should also refer to Section 1.4 "The Environmental Assessment Process," which presents a number of recommendations of relevance to the oil and gas sector.

1.5.1 Northern Oil and Gas Development

Key Challenges

Resource-based economic development in the North, particularly in the oil and gas industry, is poised for an exceptional period of growth. This important sector, in addition to the burgeoning mining industry, could significantly affect the northern and national economic landscape. It also represents a challenge to promoting sustainability and achieving balance between economic growth and social and environmental protection.

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[41] Source: Canadian Association of Petroleum Producers (CAPP), *Policy Directions for Canada's Oil and Gas Industry* (Submission to the Council of Energy Ministers - September 2003), p. 1.

[42] According to CAPP, exploration, development and operating costs in Canada are higher than in other oil and gas producing regions, such as the United States, Latin America and the Middle East. Source: CAPP, *Policy Directions for Canada's Oil and Gas Industry*, p. 4.

The Committee has heard that the development potential of the North is at risk due to the complex and unpredictable cobweb of regulations involving multiple federal government departments, and territorial and Aboriginal authorities.

At the federal level, for example, the management of northern resource development falls for the most part under the Northern Affairs Program (NAP), which is the responsibility of the Minister of Indian Affairs and Northern Development. Responsibilities under NAP include mines, oil and gas, economic development, and a range of issues related to First Nations and the Inuit. The Minister also has extensive responsibilities with respect to land, water and environmental assessment. It should be noted that the role of DIAND in the North, and the limitations of its role, is not clearly understood by many outside the federal government. In April 2003 the federal government devolved federal NAP responsibilities to the Yukon government. In the Northwest Territories, devolution discussions are progressing, although a Yukon-type approach does not appear likely in the short term since the communities involved lack a common approach to regulatory matters.

Other federal bodies also have regulatory mandates that relate to the North, including the National Energy Board, the Canadian Environmental Assessment Agency, Fisheries and Oceans Canada, Natural Resources Canada, Environment Canada, and even Foreign Affairs Canada for projects with international dimensions.

Aboriginal rights protected under section 35 of the *Constitution Act* have important implications for northern resource development. Often, First Nations and Inuit participation in the development and management of northern projects is not considered early enough by project proponents or governments, resulting in delays in regulatory decision making.

This complex situation has created an environment of regulatory uncertainty among northern regulators, regulated industries and the public in general which could jeopardize environmental protection and the development of rich and promising natural resources in the North. There are projects which could be considered in the broader national interest due to their significance and impact on the country, but which are currently beyond the capabilities of the existing regulatory framework to address efficiently and predictably. As the federal government is both the current regulator in many instances and the designer of the regulatory system in others, the Committee feels that it must show leadership and commit to resolving these issues.

This section will focus primarily on issues relating to the Mackenzie Gas Pipeline project for illustrative purposes, given its magnitude and potential impact on the region. That said, several of the recommendations put forward in the report can also apply generally to regulations pertaining to other sectors in Canada's North.

The Mackenzie Gas Pipeline and Alaska Pipeline Projects

The MGP is significant for many reasons. First, it will stimulate ongoing exploration, development and connection of new gas fields from the Mackenzie Delta-Beaufort Sea area to southern markets. Second, the primary source of natural gas in Canada comes from western reserves, which are maturing and of limited potential for increased production.

Third, development of gas reserves in Alaska's Prudhoe Bay is anticipated in the next four years. The projected pipeline serving those reserves could cross Canadian territory. Given the magnitude of the two pipeline projects, it is extremely unlikely that they would proceed concurrently. As the Alaska project is the larger of the two, the MGP has only a brief window of opportunity to get under way and be completed (assuming it receives regulatory approval) before the Alaska project is initiated. If the MGP gets delayed until after the Alaska pipeline is completed, the economies of the

MGP may have shifted to a point where the project is no longer viable. An efficient regulatory framework governing the MGP would provide investors with greater confidence in the selection of a Canadian route for Alaska gas, rather than selecting a cross-Alaska/liquefied natural gas alternative to ship gas to southern states.

The MGP Regulatory Framework

The North presents unique challenges as some of its regulatory regimes are based on claim settlement agreements that reflect the constitutionally protected rights of Aboriginal peoples.

Land claim negotiations in the Northwest Territories that are directly impacted by the MGP have involved four major groups: the Inuvialuit, the Gwich'in, the Sahtu and the Deh Cho. Three of these groups, the Inuvialuit, Gwich'in and Sahtu, have settled their land claims and actively take part in discussions to plan the future development of northern resources. The Deh Cho First Nations, which represent 13 Dene and Métis governments, have yet to settle land claims with the federal government and have expressed dissatisfaction with their role in evaluating the potential pipeline route. Forty per cent of the proposed 1,300-km MGP would stretch into the traditional lands of the Deh Cho First Nations.

During the negotiation of these land claims in the Northwest Territories, Aboriginal groups expressed a strong desire to play a greater role in regulating land and water use and in environmental assessment. As a result, the federal government enacted the *Mackenzie Valley Resource Management Act* (MVRMA), which establishes a resource management system built on a foundation of joint public boards.[43] Half the members of each board are nominated by First Nations, and half by the Minister of Indian Affairs and Northern Development or the designated territorial Minister.

The large number of boards involved in the MVRMA led to regulatory complexity. In response, the parties involved created the *Cooperation Plan for the Environmental Impact Assessment and Regulatory Review of a Northern Gas Pipeline Project through the Northwest Territories* (the Cooperation Plan). The plan involves 13 organizations:

- Canadian Environmental Assessment Agency
- National Energy Board
- Mackenzie Valley Land and Water Board
- Mackenzie Valley Environmental Impact Review Board
- Northwest Territories Water Board
- Gwich'in Land and Water Board
- Sahtu Land and Water Board
- Environmental Impact Review Board for the Inuvialuit Settlement Region
- Resources, Wildlife and Economic Development of the Northwest Territories
- Indian Affairs and Northern Development
- Environment Canada
- Fisheries and Oceans Canada
- Transport Canada

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[43] For example, the Gwich'in Land and Water Board is responsible for regulating land and water use throughout the Gwich'in Settlement Area, including Crown and Gwich'in private lands. The Board can amend, issue or renew land use permits and water licences, and set terms and conditions for the use of land and water in the Gwich'in Settlement Area.

The Cooperation Plan includes a unique joint environmental assessment process and coordinated approaches between regulators in the administration of other regulatory requirements pertaining to the MGP project. It also encourages regulators to consolidate information requirements and promotes shared technical support and public involvement.

The main objectives behind this agreement are to coordinate reviews, eliminate duplication and provide certainty regarding the processes for the MGP. Implementation of the Cooperation Plan within its pre-established timeframe would demonstrate the efficiency of a cooperative approach and help to ensure timely decision making by regulators regarding the review of the MGP.

Building on the Cooperation Plan

The MGP Cooperation Plan represents an encouraging collaborative effort by diverse regulatory authorities to address the complexity of the northern regulatory environment. It is essentially a critical short-term measure while a more robust strategy to fix the current framework is identified and developed.

However, the Cooperation Plan is not binding and is based on the good will of multiple regulators. The April 2004 signing of a "Regulators' Agreement" is a good step towards the formalization of the Cooperation Plan by reducing duplication and promoting regulatory cooperation.[44] However, some provisions of the Agreement may not go far enough. For example, parties do not face significant consequences for withdrawing from the Agreement. While it is too early to assess the Plan and the subsequent Regulators' Agreement, the Committee notes that project proponents are quite concerned that the process outlined in the Cooperation Plan will not be completed in the defined timeframe.

> **Recommendation 66: The government should continue to play a leadership role in building on the shared vision embodied by the Cooperation Plan to create a broader, long-term regulatory cooperation framework among northern regulators that offers timeliness, transparency, predictability, clarity and certainty.**

Consistency and Timeliness among Federal Regulators

Without compromising the protective elements of the northern regulatory framework, the pipeline and the oil and gas exploration industries need regulatory certainty, clarity and cooperation among key partners. The regulatory system must also be able to handle the increased workload and demand arising from these new development activities.

These industries have indicated that they are committed to fulfilling regulatory requirements (e.g. with regard to environmental assessments) but they are asking for timely and consistent decisions on whether or not they meet these requirements. The numerous regulatory authorities operating in northern regions contribute to delays in licensing and approvals, and can lead to disagreements or inconsistencies between regulatory authorities. For projects of cross-jurisdictional nature, such as pipelines, delays tend to grow in proportion to the number of regulatory authorities involved.

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[44] The signatories of the Coordination of the Regulatory Review of the Mackenzie Gas Project Agreement are: the Inuvialuit Land Administration and Inuvialuit Land Administration Commission, the National Energy Board, the Northwest Territories Water Board, the Mackenzie Valley Land and Water Board, the Gwich'in Land and Water Board, the Sahtu Land and Water Board, Fisheries and Oceans Canada, the Department of Indian Affairs and Northern Development, Environment Canada, the Government of the Northwest Territories and Transport Canada.

As described in Part I, Section 3.3 "Federal Regulatory Coordination," the use of single windows would greatly benefit both industry and citizens in terms of interacting with federal regulators. Implemented to serve an individual industry sector (e.g. pipeline industry, oil and gas exploration and development industry, etc.) the single window approach would provide a single point of contact with the entire federal government for each northern industry sector in order to provide efficient and timely service.

Recommendation 67: The federal government should implement a single window approach to coordinate the involvement of federal regulators in the regulation of industry sectors in the North (e.g. oil and gas, mining), incorporating mandatory timelines for regulatory responses to project submissions to ensure timeliness and certainty.

While the use of the single window approach would streamline interaction with specific industry sectors, the use of a federal coordinator could enable the federal government to speak with one voice on issues related to specific, large-scale investment projects in the North, such as the MGP. In the case of the MGP, a coordinator could also work with other regulators outside the federal jurisdiction to ensure the constant and careful nurturing of the Cooperation Plan, foresee obstacles and work towards consensus-based solutions that will ensure timely decision making.

The Committee is encouraged by the recent federal announcements regarding the establishment of a northern energy office to act as a "storefront" to the federal government, and the appointment of a ministerial representative who will provide advice to the ministers of Indian Affairs and Northern Development and Natural Resources Canada on issues related to the MGP. While the ministerial representative will play a vital role in facilitating public communications among all stakeholders related to the project, the Committee feels that a federal coordinator role is also required. This coordinator would have clear decision-making authority and accountability in order to implement a coherent regulatory environment for the MGP and ensure public transparency.

Recommendation 68: To encourage the efficient regulation of the Mackenzie Gas Pipeline, it is proposed that a federal coordinator be appointed as soon as possible with clear decision-making authority vis-à-vis the various departments and accountability to implement a coherent regulatory environment for the MGP.

Capacity Building

Given northern demographics, there is a need to develop regulatory capacity in Aboriginal communities in line with the federal Aboriginal self-government policy. Aboriginal approval boards are faced with complex and time-sensitive issues with important consequences for the future of their communities and for Canada. These boards, for example, are required to carry out extensive and complex environmental assessments. In general, they have been formed only recently as a result of the devolution of power from the federal government. Many stakeholders expressed concern that the federal government does not fully appreciate the impact of these developments on the regulatory environment in the North. Significant measures are needed to help build Aboriginal skills and capacity so that Aboriginal communities can be full and productive participants in regulatory processes (see also Section 1.3. "Enabling First Nations Economic Development").

Recommendation 69: The federal government should provide training for all new northern regulatory board members as a condition of appointment and as ongoing support. The federal government should also work with similar boards and tribunals across northern Canada to create a network to share best practices and solutions to the challenges facing them.

1.5.2 Offshore Oil and Gas

Over a few decades, in excess of $40 billion has been spent in exploration and development activities in Canada's offshore. Oil production contributed to Newfoundland and Labrador recording the fastest-growing economy in Canada in 2002, while industry spending offshore of Nova Scotia hit almost $1 billion in 2002.[45] Nevertheless, the level of exploration activity on the East Coast has been sporadic and too low to create a vibrant industry. It is a high-cost area of uncertain potential.

Offshore oil and gas exploration and development is potentially broader than just the waters off Nova Scotia and Newfoundland, where development has been concentrated to date. The Committee focused its attention on the Atlantic offshore, but that region may offer lessons for other areas as well.

Interest in East Coast exploration, for example, is extending into new areas like the Gulf of St. Lawrence and the Bay of Fundy. While development in these new offshore areas would benefit from clear regulatory structures, these regulatory frameworks should not add to the complexity of the East Coast offshore by diverging from the existing Newfoundland and Nova Scotia regulatory approaches.

In British Columbia, the offshore is currently subject to a federal moratorium, which is under review. A key issue is to identify, based on scientific data, the areas in which the moratorium could be lifted safely if this was the policy choice for this region. Aboriginal claims regarding the resource must also be taken into account. The Committee was encouraged that the province has put in place a team to examine the experience in Atlantic Canada and in other offshore production regions around the world to identify regulatory best practices for adoption in B.C, should a decision be taken to allow offshore oil and gas development in this region.

Lastly, the shallow waters offshore of the Mackenzie Delta in the Beaufort Sea present significant development potential once the Mackenzie Gas Pipeline project is confirmed. This area shares much of the same complex regulatory environment discussed previously in Section 1.5.1 "Northern Oil and Gas Development," as well as issues of regulatory interface between onshore and offshore development (e.g. linkage of offshore resources to onshore pipelines). Drilling at a significant scale cannot be expected until a clear decision has been made to proceed with construction of the Mackenzie Gas Pipeline, for fear of stranding investment dollars in unserviceable wells. As has been noted, the federal government must continue its efforts to clarify and provide leadership in the regulatory environment in the North, particularly in areas of sole federal responsibility.

In all these regions, the regulatory environment should help foster exploration and development activities in these new areas. At the same time, it must continue to take into account other ocean-based sectors, such as the fisheries industry, and overall environmental sustainability goals.

Key Challenges

As stated at the outset of this section, there is growing, intense competition both with more established and emerging offshore jurisdictions in places such as the Gulf of Mexico, Chile and the North Sea for investment dollars and commitment to offshore exploration or extraction activities. Given the capital required to maintain operations in sometimes extreme environments (such as the North Atlantic), the regulatory system for the offshore is an important component of project costing and scheduling and can affect underlying project economics. A government that can design responsive regulatory frameworks that encourage responsible and sustainable resource extraction while minimizing cost, uncertainty or delay will have a strategic advantage.

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[45] Source: Canadian Association of Petroleum Producers.

The Committee heard that the current regulatory framework for the offshore falls short of these objectives. For example, according to industry sources, the average regulatory approval time for projects in Canada's Atlantic offshore exceeds 600 days, compared to approximately 200 days in the United Kingdom and Norway and just under 400 days in the Gulf of Mexico.[46]

The offshore regulatory environment reflects the realities of Canada's constitutional division of powers in the multiple approvals, authorities, and legislative and regulatory frameworks that exist (some of which are largely but not fully parallel to each other). These parallel approaches can lead to confusion about which regulations are paramount or to duplication, for example, where a rig going from Newfoundland to Nova Scotia must be certified by each jurisdiction.

The regulatory framework developed for the East Coast offshore oil and gas industry has a number of distinguishing features, for example:

- there are parallel federal-provincial legislation and regulations (the *Canada-Newfoundland Atlantic Accord Implementation Act* and the *Canada-Nova Scotia Petroleum Resources Accord Implementation Act*);
- joint management regimes exist, with independent boards created to manage development on behalf of both levels of government; and
- provinces set royalty levels and receive all revenues as if resources were on land.

The regulatory environment involves the Canada-Nova Scotia Offshore Petroleum Board and the Canada-Newfoundland Offshore Petroleum Board, which administer exploration, development, extraction, production operations, construction, certification, health and safety and pipeline facilities in their respective regions. The National Energy Board is responsible for international and/or interprovincial regulatory issues and certain operating certificates related to pipeline facilities, as well as regulation in all non-Accord areas. The Canadian Environmental Assessment Agency is responsible for administering the federal environmental assessment process in combination with relevant departments.

The protection of marine habitats and environments falls under the responsibility of Environment Canada, the Canadian Environmental Assessment Agency and Fisheries and Oceans Canada through the environmental assessment process, the principles set out in the *Oceans Act*, and the mandates for habitat conservation and protection. Further, in some cases, Marine Protected Areas (Fisheries and Oceans Canada) and Marine Conservation Areas (Parks Canada) are established to achieve this purpose. There is a large measure of shared responsibility, which leads to the potential for confusion and inefficient cross-jurisdictional oversight.

This complex structure has led to a lack of clearly applied timeframes for each step of the regulatory process, resulting in a lack of predictability and timeliness in decision making. The structure also acts as a disincentive, particularly for smaller firms, to invest in the region. The Committee heard that the presence of multiple regulators also makes it difficult for interested citizens to participate in the regulatory process.

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[46] CAPP, *Policy Directions for Canada's Oil and Gas Industry*, p 6

The Oceans Act

The oil and gas industry is one of several users of the ocean resource. Others include fisheries, aquaculture, tourism and transportation. The federal government has created a mechanism, through the *Oceans Act*, to plan the activities taking place in Canada's oceans and establish criteria for sustainable economic development of ocean space in a way that considers the interests of all of these users while protecting the marine environment. This approach is based on the premise that key players must be willing to cooperate on planning the use of oceanic space.

This represents a new approach whereby the federal government, in cooperation with all stakeholders, will promote the sustainable development of Canada's oceans and their resources. At the same time, this approach should increase operating efficiencies and business security through greater harmonization of approval and regulatory processes for marine and coastal use. For example, it should help to generate earlier awareness and understanding of exploration and development interests among regulators and other users as well as proactively identify those areas where activities, like oil and gas projects, will not likely be approved or will require additional research or protection measures.

Much of the ecosystem-based approach outlined in the *Oceans Act* is consistent with many of the Smart Regulation principles proposed by the Committee. As Fisheries and Oceans Canada implements the approach, it will address some of the concerns regarding the regulation of offshore oil and gas activities. For example, the use of strategic environmental assessments (as outlined in Section 1.4 "The Environmental Assessment Process") would advance planning and streamline management of marine-use activities like offshore oil and gas.

At the same time, the Committee notes that since it came into force in 1997, the potential benefits of the *Oceans Act* have not yet been fully realized. While it recognizes that the Act is being implemented in a planned and systematic manner, the Committee has heard from industry that the delay in its implementation has contributed to the regulatory uncertainty in the sector.

The legislated requirement for a national strategy for the management of Canada's oceans has been met with the release of *Canada's Oceans Strategy* (COS) in 2002. COS specifically recognizes the importance and contribution of the offshore oil and gas industry in supporting sustainable economic opportunities. Fisheries and Oceans Canada has implemented integrated management and planning initiatives in areas of importance to offshore oil and gas exploration and development in the Atlantic, Arctic and Pacific oceans. These priority planning areas have been selected (in part) due to existing or potential oil and gas development. Progress has been made in identifying and protecting environmentally sensitive areas. For example, as part of Fisheries and Oceans Canada's efforts to maintain environmental quality for living marine resources, it is focusing on the impact of noise on the marine environment, including seismic exploration. Existing regulations concentrate only on the health and safety aspects of seismic surveys.

By specifying in legislation when, where and how seismic activities can be undertaken, the government will give stakeholders a more predictable regulatory regime. These standards are intended to complement processes under the *Canadian Environmental Assessment Act* as well as future Regional Strategic Environmental Assessments.

That said, the Committee has heard concerns from provincial regulators and industry that the eventual development of these new seismic regulations by Fisheries and Oceans Canada under the *Oceans Act* could conflict with existing regulatory frameworks for offshore areas. The *Oceans Act* represents an opportunity to improve regulatory coherence for Canada's offshore regions, and any proposed legislation would be consistent with the principles of the Smart Regulation initiative.

Recommendation 70: As Fisheries and Oceans Canada proceeds to develop regulations under the *Oceans Act*, it should ensure that these measures are established in consultation and collaboration with other federal and provincial regulatory authorities, industry, First Nations and other stakeholders. This approach should complement existing regulations governing offshore oil and gas seismic activities.

Improved Regulatory Structure

While the multi-jurisdictional structure of the offshore is intended to achieve important policy goals and priorities, such as economic growth and environmental sustainability, its complexity has led to uncoordinated approaches that are costly, can limit access and flexibility for applicants, citizens, interest groups and even other levels of government, and create a lack of transparency and predictability. Given these challenges, an overarching regulatory policy framework is required to guide the activities of federal departments. This approach should align existing and proposed regulations and foster clear and integrated regulatory approaches in areas such as safety, environmental compliance, security and conservation of the resource. By establishing concrete policy objectives for the sector, a regulatory framework would also establish standards to gauge the effectiveness of the regulatory structure.

In an encouraging development, a process has been mapped out through the Atlantic Energy Roundtable to develop an agreement that would create definite timelines, standardize information requirements, create generic procedures and ensure public consultation under a joint or coordinated federal-provincial approach to project review. The work of the Roundtable has produced concrete results with the development of a Memorandum of Understanding (which recently completed the public consultation process) that seeks to implement environmental assessments and other regulatory processes in the offshore Accord areas (i.e. Nova Scotia and Newfoundland) in a concurrent and coordinated manner.

Many stakeholders have expressed a broader concern over the lack of "follow through" by the federal government once large-scale initiatives have been launched. This issue is discussed at greater length in Part I, Section 3.6 "The Regulatory Process." In the case of the Atlantic Roundtable, while the recently signed MOU represents a good start in coordinating regulatory activities in the Atlantic offshore, federal leadership and effort will be essential to achieving the goals of the MOU.

Recommendation 71: Federal government interaction with the offshore oil and gas industry and other stakeholders should be guided by an overarching regulatory policy framework linking all relevant federal departmental responsibilities.

Performance-Based Approaches to Regulation

The regulatory approach to the industry is largely prescriptive in nature. It is based on specific requirements set by government for a host of expectations. Prescriptive regulation is typically based on the technology known at the time the regulations were drafted. In a sector like oil and gas exploration, where the technology is progressing rapidly, the prescriptive approach can discourage innovation as it has difficulty accommodating new technology that can improve environmental performance and project economics. The large number of requests from the offshore oil and gas industry to deviate from specific regulations and take different approaches is evidence of this problem. As a result, new technology is adopted in an ad hoc manner.

Performance-based approaches present an alternative, but will not be appropriate in all circumstances. A hybrid of prescriptive and performance-based approaches may be needed in some cases to provide prescriptive solutions for regulatees who cannot develop performance-based solutions (such as small and medium-sized enterprises) or who seek regulatory certainty. While performance-based regulation increases flexibility, it also increases the burden on regulators and project proponents, both of whom must demonstrate that regulatory objectives are being met. It is a complex challenge that will take time to address. A good starting point would be those regulatory areas where there have been a greater number of deviation requests.

> **Recommendation 72: Performance-based regulation should be developed in areas that would enable safety and environmental approaches to be adapted to specific risks as they are encountered, and new technology to be incorporated quickly, while meeting economic, social or environmental regulatory performance expectations.**

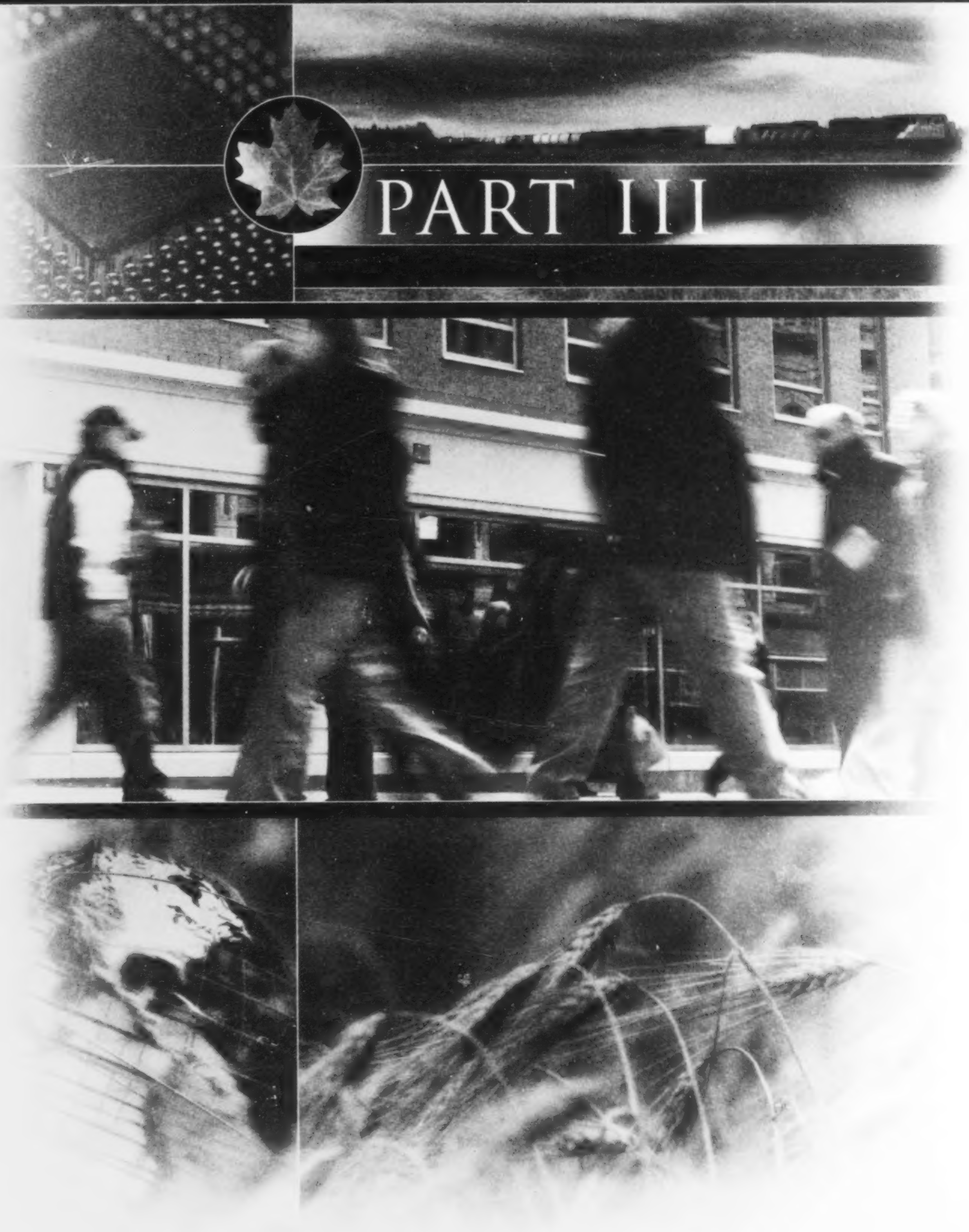
Enhanced Environmental Assessment Procedures

In July 2003, the federal government extended application of the *Canadian Environmental Assessment Act* to cover East Coast offshore oil and gas drilling. It did so to ensure that in parts of Canada where offshore oil and gas activity is permitted federally, exploration and production activities will be subject to the same environmental assessment process. Under the CEAA, the first exploratory well in a new area of the offshore requires a comprehensive study, whereas the previous approach under the offshore boards had been equivalent to a screening review.

As discussed briefly in the section on the environmental assessment process, the primary differences between screening reviews and comprehensive studies are the complexity and length of the process and the extent of public consultations, which are greater for comprehensive studies. For example, unlike a screening review, a comprehensive study must look at alternative means of carrying out the project and the capacity of renewable resources to meet present and future needs. Monitoring requirements under a comprehensive assessment can also be more rigorous. However, industry representatives still question the rationale as to why these drilling activities require the additional rigour of comprehensive studies rather than screening reviews.

The Committee notes that the Canadian Environmental Assessment Agency is currently working with a subcommittee of the Minister of the Environment's multistakeholder Regulatory Advisory Committee to examine whether offshore exploratory wells should remain on the comprehensive study list. The subcommittee consists of representatives from industry, federal departments, environmental non-governmental organizations, provincial agencies and Aboriginal organizations.

> **Recommendation 73: The government should ensure that the multistakeholder Regulatory Advisory Committee studying the policy, which requires comprehensive study assessments of exploratory wells, completes its deliberations and takes appropriate action in a timely manner.** ◆



PART III

MAKING IT HAPPEN

The Committee recognizes that the scope of its report is large and that the recommendations it proposes are ambitious. The Committee often heard that the problem with the regulatory system is not one big issue but many little issues, which make the system daunting for those who have to understand and comply with it. These kinds of issues call for change at the strategic, organizational and cultural levels. They have important implications for departments, which must find new and different ways to achieve their missions.

Such a transformation will not happen without strong political leadership at the most senior levels. The federal public service will need clear direction and support from the government to implement these changes. The government must be accountable for setting a course of action and the public service for implementing it promptly. The responsibility is upon parliamentarians, provincial and territorial governments, industry and businesses, non-governmental organizations and interested citizens to work together with the federal government and take an active part in the transformation of the regulatory system. A willingness to share issues, an open mind to listen to other perspectives, and a commitment to finding solutions in the interest of all Canadians and the future of the country are preconditions without which the proposed changes will not happen. This is why the Committee has insisted on cooperation as a key theme of its report.

During the course of its mandate, the Committee often heard that one of the biggest challenges to Smart Regulation would be its sustained implementation and translation into new departmental practices. One of the key issues with the current regulatory policy is that it has yet to be fully or consistently implemented by departments and agencies. The main barriers to its implementation include the following: the lack of recognition of the importance of regulation by ministers and parliamentarians; the lack of attention regulation gets relative to spending and taxation measures; the resistance to change within individual departments; and the lack of accountability and related mechanisms with respect to the application of, and compliance with, the regulatory policy.

Indeed, during the Committee's consultations, many people questioned the federal government's willingness and ability to implement the kind of changes proposed by the Committee. Federal officials showed interest in and support for its work. Even so, the Committee feels that it is necessary to bring this issue to the attention of government and that this third part of its report should be dedicated to the issue of implementation. The nine initiatives in this section constitute a short-term action plan to be initiated and implemented within the next 18 months, to the greatest extent possible. This short-term plan is intended to "kick start" the government's implementation of Smart Regulation.

At present, there is a great deal of interest across the country in transforming the regulatory system. The Committee has witnessed — and hopes that it has contributed to developing — considerable momentum behind regulatory reform. There is an opportunity therefore to take action and develop a system that will be consistent with the values and aspirations of all Canadians and will ensure that Canada is well positioned in the future to take advantage of opportunities and offer its citizens a continued high quality of life.

These changes will not happen overnight. The agenda put forward by the Committee will take a few years to implement, but it is important to start now. The Committee therefore proposes the following immediate actions to drive the successful implementation of Smart Regulation.

1. Transitioning to Smart Regulation – The government should commit to making all new regulation "smart." In the short term, one way to achieve this (until the regulatory process has been modified and a new policy is developed) is to ask departments and agencies to add a section to the Regulatory Impact Analysis Statement to demonstrate how the proposed regulation is consistent with a Smart Regulation approach. This will require direction and leadership from the Privy Council Office. Over the longer term, the way PCO exercises its challenge function should be strengthened. PCO should lead and manage a federal regulatory agenda to enable effective priority setting and support departments in implementing Smart Regulation.

2. Developing a regulatory policy for the 21st century – The government should develop a new federal regulatory policy by September 2005 embodying the vision and principles as well as the directions proposed by the Committee.

3. Supporting a learning regulatory community – The quality of the regulatory system, and the success in changing approaches, lies in better supporting and developing the skills, competencies and capacity of the people who work in regulatory programs and areas. An essential initial step in effecting a regulatory "cultural change" is to implement a Smart Regulation learning strategy for the regulatory community. Such a strategy would include the sharing of best practices, mobility across departments, orientation courses and a system to disseminate knowledge across regulatory departments and agencies.

4. Developing multistakeholder "swat teams" – Based on the principle of cooperation and on the recommendation to review the current stock of regulation, "swat teams" for industry sectors should be established to help lead regulatory reform processes. In addition to the relevant federal departments, these teams would include representatives from industry, provincial/territorial governments, Aboriginal organizations, non-governmental organizations, Canadian scientists from universities or centres of excellence and others as appropriate. Their objective would be to make recommendations to ensure that regulation affecting an industry sector is "smart." Swat team members should be committed to the protection and enabling principles of Smart Regulation and participate in a spirit of cooperation to develop common solutions. They should also commit to dedicate the time and effort necessary to implement the recommendations.

The swat teams would be given a six-month term of reference to do the following:

- identify regulatory issues that can and should be addressed immediately;
- identify issues with a broader scope that will require other departments and stakeholders to resolve them (e.g. the *Competition Act* and intellectual property issues); and
- develop work plans for more complex, long-term issues.

The swat teams would report to a designated minister. As an initial step, three swat teams should be created by December 2004, with the commitment to cover all sectors of the Canadian economy by the end of 2007. After their reports have been tabled, progress on implementing the swat team plans should be assessed and reported on regularly. Many industry sectors have expressed interest in this concept and are prepared to commit the necessary time and effort to be involved. These sectors include forest products, food, oil and gas, and air transportation.

5. Simplifying the environmental assessment process – The Minister of the Environment should initiate discussions immediately with the provinces and territories to explore the possibility of creating a national approach for environmental assessments. The situation should be assessed by June 2005. Should there be no interest from provincial and territorial governments or if progress is too slow, the federal government should create a single federal environmental assessment agency and implement other measures to improve the environmental assessment process.

6. **Improving federal-provincial-territorial cooperation** – Addressing coordination issues between orders of government is an essential step in developing more coherent regulatory approaches in Canada. Developing a cooperative Smart Regulation approach should be identified as an agenda item for a forthcoming First Ministers' meeting. Environmental assessments should be a priority for discussion.

7. **Addressing regulatory gaps in First Nations communities** – The government should move quickly to address regulatory gaps (e.g. in the areas of health, safety, and environmental protection and enforcement) that inhibit the development of commercial and industrial projects and other economic activity on reserve lands. The government should commit to provide First Nations communities with the appropriate regulatory framework to launch economic development projects within the next 12 months.

8. **Reducing small regulatory differences between Canada and the U.S.** – The Committee has highlighted the myriad small differences between Canadian and American regulations as an important issue and recommends that they be reduced or eliminated. The federal government should take immediate steps in this regard. A designated minister should invite interested stakeholders to identify, by the end of December 2004, those regulatory differences for which elimination would not impede Canadian social (including health and safety) and environmental objectives. Each should be examined against the set of criteria for specific Canadian requirements proposed by the Committee. By June 2005, recommendations should be made to the relevant ministers, who should take steps to immediately implement the recommendations.

9. **Enhancing access to the federal government** – The federal government should establish mechanisms in the next six months to provide an opportunity to stakeholders and citizens to challenge regulatory performance and decisions. The authority given to such mechanisms could include mediation, investigation, convening public hearings and making recommendations.

To complement these actions, the Committee recommends that the government develop and implement a strategy to broadly promote Canada's commitment to Smart Regulation. As progress is achieved, it should be communicated within Canada to encourage stakeholders' commitment and reinforce the need for their cooperation to continuously improve the regulatory system. This would help to ensure that the regulatory community's work is recognized and that it takes pride in its successes. Opportunities outside Canada should be identified to make sure that potential foreign investors and consumers of Canadian products trust the Canadian regulatory system and perceive it in a positive light.

Parliamentarians have an essential role in the regulatory process in terms of representing the interests of Canadians and providing leadership on regulatory directions for the future. Parliamentarians should be engaged in redefining relationships within a Smart Regulation system.

Finally, it will be important for the government to monitor and report to citizens regularly on progress in the implementation of Smart Regulation. 🍁

EXTERNAL ADVISORY COMMITTEE ON SMART REGULATION

We, the Members of the External Advisory Committee on Smart Regulation, are pleased to present this report and believe that the realization of its vision will benefit Canadians in the 21st century.

Mr. Gaëtan Lussier, Chair

R. Burak

Ms. Rita Burak

Mr. Bernd S. Christmas

Dr. Robert B. Church

Mr. Richard Drouin

Mr. Scott H. Jacobs

Ms. Louise Rozon

Mr. David Runnalls

Mr. Raymond I. Woods

R. J. Wright

Mr. Robert J. Wright, C.M., Q.C.

ANNEX I: PAPERS COMMISSIONED BY THE EXTERNAL ADVISORY COMMITTEE ON SMART REGULATION

de Mestral, A.L.C. *Study of International Regulation.* 2003.

*Hart, Michael. *Risks and Rewards: New Frontiers in International Regulatory Cooperation.* 2003.

Leiss, William. *Smart Regulation and Risk Management. 2003.*

Löfstedt, Ragnar E. *How Can Better Risk Management Lead to Greater Public Trust in Canadian Institutions: Some Sobering Lessons from Europe.* 2003.

Mendelsohn, Matthew. *A Public Opinion Perspective on Regulation.* 2003.

Pal, Leslie A., and Judith Maxwell. *Assessing the Public Interest in the 21st Century: A Framework.* 2003.

Priest, Margot and Eric Milligan. *A Synthesis Report Based on a Review of Regulatory Management Practices in Select OECD Countries and the European Union.* 2003; *Regulatory Management Assessment: Australia.* 2003; *Regulatory Management Practices in Finland.* 2003; *Regulatory Management Practices in the United Kingdom.* 2003; *Regulatory Management Practices in the European Union.* 2003; *Regulatory Management Assessment: United States.* 2003.

Stratos Inc. *Economic Instruments for Environmental Protection and Conservation: Lessons for Canada.* 2003.

Zacher, Mark W. *International Health Governance — Surveillance, Regulation and Material Assistance: Trends and Lessons for the Future.* 2003.

To view the papers in full, visit www.smartregulation.gc.ca.

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* Paper co-commissioned by the Department of Foreign Affairs and International Trade and the External Advisory Committee on Smart Regulation

ANNEX II: A PUBLIC INTEREST ACCOUNTABILITY FRAMEWORK (PIAF)[47]

In writing decisions, regulatory tribunals should conclude with an explanation of the tradeoffs that have been made in order to protect the public interest. This is a two-stage process.

PIAF Stage I Review of the Evidence

1. Has due process been followed in constructing the regulatory decision-making process, and can we with confidence say that decisions that result from that process have been shaped fairly? Key benchmarks here are accessibility, transparency (distribution and availability of information), mechanisms for participation and deliberation, accountability and neutrality in decision-making.
2. What is the state of Canadian public opinion on the issue? Are there clear majority views on various aspects of the issue?
3. Which specific interests are connected to the issue, and what are their views? How are the costs and benefits of different regulatory options distributed among these groups and more generally among the Canadian population?
4. What are the key common interests or public goods at stake in this area — examples would include health, security, safety, environmental protection, future generations, innovation, competitiveness. How are risks assessed? What is the balance of these common interests?
5. Are there shared values or normative guidelines that affect decision-making in this area? Are there specific legal rights of either individuals or collectivities that should be referred to in the decision-making process?

PIAF Stage II Balancing the Interests

A statement of how the decision has struck the balance among the interests at play in the proceedings — including those of the consumers, businesses, individual and collective interests.

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[47] *Assessing the Public Interest in the 21st Century: A Framework*, by Leslie A. Pal and Judith Maxwell

ANNEX III: A PROPOSAL FOR A NEW REGULATORY POLICY FOR CANADA

Our Pledge to Canadians

The Government of Canada will work with citizens, businesses and other governments to enhance our national regulatory system in order to maximize the benefits of regulation for all Canadians, enable Canadians to take advantage of new knowledge and support Canada's participation in a dynamic global economy.

The Government of Canada is committed to:

- instilling trust, confidence and credibility at home and abroad in Canada's regulatory system and in Canadian products and services, markets and government institutions;
- ensuring that our national regulatory system encourages innovation, market performance, competitiveness, entrepreneurship and investment in the Canadian economy; and
- demonstrating to citizens that the regulatory system will safeguard the Canadian public interest, which includes such issues as human health and safety and environmental protection, within dynamic global markets.

Scope of Policy

This policy recognizes that regulation is a form of intervention that is not limited to primary and secondary legislation but also includes a variety of instruments which are more effective when used as part of a mix. This policy sets out the commitments that will guide the Government of Canada when making decisions on whether to use regulatory intervention, what form of regulation to use and how to ensure that regulatory action accomplishes its objectives. The policy applies to all aspects of the regulatory process, including the development, administration, implementation and enforcement of regulation and regulatory programs.

Context

Regulation is an essential and valuable tool for achieving public policy objectives, advancing national priorities and furthering the public interest. With this policy, the government commits to employing regulatory intervention, in conjunction with other instruments, where necessary and appropriate to protect and enhance the welfare of present and future generation of Canadians. The concept supporting this policy is that the relationship between economic performance, environmental quality and social/human welfare is interlinked and that regulation should advance these objectives concurrently wherever possible.

The government recognizes that Canadians are currently experiencing a time of rapid scientific and technological change, heightened expectations of government for individual, economic and national security, and the accelerated flow of trade and movement of people throughout the world. Regulatory intervention, whether it is at the development, administration, implementation or enforcement stage, must adapt constantly to these changes in order to ensure the protection of the health and safety of Canadian citizens, the promotion of sustainable development, the efficiency and fairness of the marketplace as well as the creation of a business environment supportive of innovation and investment.

This rapidly changing environment brings both opportunities and risks that can be effectively addressed only through the collective action of individual Canadians, the governments that serve them, businesses, voluntary sector organizations, foreign governments and international organizations. Increased cooperation between these players will contribute to solutions to regulatory issues that will be in the public interest and that will maintain and increase trust in the regulatory system. Business people, representatives of non-governmental organizations and individual Canadians are therefore expected to play a role, not only in the process of devising regulatory policy, but also in seeing that the promise of the policy is translated into concrete results.

Statement of Commitments

The policy is based on the following principles: effectiveness, timeliness, cost-efficiency, transparency, and accountability and performance.

Effectiveness

The government is committed to ensuring that regulation is aligned in a coherent and integrated manner within the federal government to advance government policies and priorities.

> *The efficient coordination of various regulatory authorities is central to a well-functioning regulatory system. Federal departments and agencies will coordinate their actions in the development of new regulatory intervention and in the administration and implementation of existing regulation. This policy commits the government to ensuring that relevant federal organizations coordinate their regulatory interventions to maximize the effectiveness and achievement of policy objectives. Regulators must understand the cumulative impact of regulation and seek to avoid overlap, duplication and inconsistency.*

The government is committed to working cooperatively wherever possible with other jurisdictions, both within Canada and internationally, when studying regulatory issues and designing regulatory interventions.

> *The government is committed to cooperating with the provincial and territorial governments to create a seamless regulatory environment in Canada. It will also adopt international approaches wherever possible. Regulatory differences between Canada and its major international partners will be minimized. Specific Canadian requirements may be appropriate when there is no commonly agreed upon international or North American standard, when the federal government is pursuing important national priorities, or when there are unique Canadian circumstances or constitutional values requiring different approaches. When specific Canadian requirements are adopted, the government will seek to reduce or minimize the cumulative impact of regulatory differences. When developing or modifying regulation, federal regulatory authorities must make sure that international and intergovernmental agreements are respected.*

The government is committed, before taking regulatory action, to ensuring that it has a sound and scientific understanding of those risks requiring regulatory action, the forces that will cause those risks to change in the future and the consequences of any action the government may take to manage those risks.

> *Regulation will reflect the latest and best knowledge. An analysis of risks and how they change over time is the foundation for regulatory impact analysis. The government must demonstrate that a problem or risk exists and that federal government intervention is justified. The government is committed to developing a thorough understanding of the problem that is prompting regulatory intervention, with a focus on the set of factors that are influencing the risks and how those risks may evolve in the future. The government will seek the knowledge of Canadian and international experts, particularly in regard to the nature and significance of the risks being addressed and to the*

> *design of regulatory measures. It is recognized that the government does not make public policy decisions solely on the basis of advice provided by scientists, economists, mathematicians, statisticians, lawyers or any other type of expert, but that it will consider this kind of evidence when making a regulatory decision.*

Cost-Efficiency

The government is committed to establishing priorities for regulatory intervention, risk reduction and the administration of regulatory programs and is committed to being prudent in applying the resources provided by Canadian taxpayers.

> *The government will adopt a principled and predictable approach to risk management and, in particular, to priority setting for new regulatory interventions. The government will exercise prudence in allocating regulatory resources consistent with its stewardship role. It will also ensure that it has the necessary resources to discharge its enforcement responsibilities and ensure compliance with regulation.*

The government is committed to designing and implementing regulatory intervention in a way that maximizes the benefits and minimizes the costs for all Canadians.

> *Regulatory intervention must generate "net benefits" for society, which will include social, environmental and economic factors. Regulatory action will be commensurate with the scope of the risk or problem. A variety of regulatory and policy approaches will be evaluated to determine the optimal mix of policy interventions to produce the greatest net benefit. The government will recognize and take into account the circumstances under which small and medium-sized enterprises operate when it regulates.*

Timeliness

The government is committed to ensuring that regulatory development and decision making reflect the latest knowledge and that regulatory programs are regularly reviewed to maintain their relevance and effectiveness in achieving the intended results.

> *Regulation should be based primarily on standards and performance targets. Regulatory measures must be regularly and systematically reviewed and, when necessary, eliminated or modified to ensure responsiveness. New measures should be created to take into account progress towards the policy objective, consumer needs, citizens' expectations, scientific and technological advances and the changing business environment.*

The government is committed to making decisions and implementing regulatory requirements in a timely manner.

> *The government is committed to ensuring timely and predictable action for the design of regulation, decision making and implementation. When appropriate, service standards and timelines will guide the development of regulation and decision making. In circumstances where an issue is particularly complex or when available evidence is not conclusive, it may be in the public interest to delay a decision. In those circumstances, relevant stakeholders will be informed and advised of the rationale for the delay.*

Transparency

The government is committed to developing, approving and implementing regulatory policies and decisions in an open, transparent and inclusive manner.

> *A regulatory culture that emphasizes and encourages openness, transparency and inclusiveness is a prerequisite for building public trust in Canadian regulation and the integrity of the process. Transparency is central to meaningful accountability and continuous improvement of regulatory performance. Government decision making will be transparent and timely in providing the rationale for decisions. The government is committed to providing stakeholders with opportunities to meaningfully challenge both the performance and decisions of regulators. Stakeholders who cannot resolve an issue directly with a regulator will have access to effective recourse mechanisms, allowing for complaint resolution and the provision of whole-of-government positions.*

The government is committed to consulting broadly with Canadians, businesses and citizens' groups when developing new regulatory requirements and revising existing ones.

> *A new cooperative relationship between governments at all levels, citizens and business is the basis of smart regulatory governance. They need to participate in all aspects of regulatory governance through active consultation and engagement. The government will put in place the conditions that will facilitate the participation of all interested parties and citizens. The government is committed to communicating and sharing information with Canadians about regulatory issues and the consequences of various regulatory and policy options in a clear, open and timely manner. This commitment points to a relationship that is based on trust and an understanding that regulatory solutions require input and advice from a broad cross-section of society. Regulatory and policy development will be most effective if it is implemented as a process of collective learning.*

Accountability and Performance

The government is committed to explaining to Canadians how a new regulatory intervention is in the public interest and specifying the results expected from regulatory intervention. The government is committed to monitoring its regulatory performance, providing meaningful reports to Canadians and ensuring accountability for the results generated through regulatory action.

> *Performance monitoring and management practices as well as effective accountability are essential to an effective regulatory regime. Proposals for new regulatory intervention must incorporate and communicate explicit performance expectations with respect to regulation. The government will establish and operate an effective accountability regime that is focused on results. The government will sustain its capacity and strive for continuous improvement in its ability to develop regulatory policy and to administer and enforce regulatory programs.*

Note: This policy should be supported by a series of documents (e.g. a public interest accountability framework) providing detailed guidance for government officials on the regulatory process and analytical requirements. The documents should be available to the public via the Privy Council Web site (www.pco-bcp.gc.ca). They should also spell out the roles and responsibilities of all the actors in the regulatory system, including the different federal authorities, interested stakeholders and citizens.

ANNEX IV: RECOMMENDATIONS

PART I: STRATEGY

International Regulatory Cooperation

Recommendation 1: The federal government should include international regulatory cooperation as a distinct part of Canadian foreign policy. To this end, it should develop a strategic policy framework for international regulatory cooperation that identifies priorities for coordinated federal and national action. The framework should provide guidance in the following areas:
- the design and implementation of regulation in Canada;
- an agenda for regulatory cooperation in North America; and
- Canada's key bilateral and multilateral relationships.

Recommendation 2: When developing new regulatory frameworks, the federal government should review and adopt international approaches wherever possible. The federal government should limit the number of specific Canadian regulatory requirements.

Recommendation 3: Specific Canadian regulatory requirements may be appropriate when:
- there no commonly agreed upon international or North American standard;
- important national priorities, unique Canadian circumstances or Constitutional values require different approaches; or
- the government does not have sufficient confidence that the regulatory processes, practices, results and/or decisions of a trading partner will meet Canadian policy objectives.

Recommendation 4: Where specific Canadian regulatory requirements are adopted, the federal government should reduce or minimize the cumulative impact of regulatory differences on trade and investment by:
- assessing alternative instruments for meeting policy objectives (e.g. voluntary measures, information strategies);
- promoting the use of performance-based approaches where possible; and
- establishing the appropriate accountability structures to review requirements regularly to ensure that policy objectives are being met and eliminate those regulations that are no longer necessary.

Recommendation 5: North America should be the primary and immediate focus of the federal government's international regulatory cooperation efforts. The federal government should work to:
- achieve compatible standards and regulation in areas that would enhance the efficiency of the Canadian economy and provide high levels of protection for human health and the environment;
- eliminate small regulatory differences and reduce regulatory impediments to an integrated North American market;
- move toward single review and approval of products and services for all jurisdictions in North America; and
- put in place integrated regulatory processes to support key integrated North American industries (e.g. energy, agriculture, food) and provide more effective responses to threats to human and animal health and the environment.

Recommendation 6: The federal government should work with its U.S. and, where appropriate, Mexican counterparts to build mutual trust and confidence in each other's regulatory processes and decisions through the increased use of independent peer reviews of these regulatory processes, information sharing, shared data collection and risk assessment methods, common decision-making procedures and joint reviews.

Recommendation 7: Canada should promote joint and single product reviews for multiple markets. Canada should also move toward accepting the approvals and reviews of products by its U.S. and EU trading partners in sectors where there are well-established, internationally recognized conformity assessment procedures already in place.

Recommendation 8: Canada should identify and target the areas where it wants to be an international leader, focusing on those areas that will produce maximum benefit for Canadian citizens and businesses, for example biotechnology, natural resource development and cultural diversity.

Federal-Provincial-Territorial Regulatory Cooperation

Recommendation 9: The federal government should pay urgent attention to creating a more seamless regulatory environment in Canada. Federal-provincial-territorial cooperation should be formalized in a new joint arrangement between governments, to be initiated through a discussion involving First Ministers. The new process should focus on key priorities (e.g. environmental assessments), identify and address impediments to cooperation, develop a framework to guide regulation making, and publish regularly on the state of regulation in Canada.

Recommendation 10: The federal government should ensure the early involvement of provincial and territorial governments in developing Canadian positions on international regulatory issues that have an impact on their jurisdiction, and the two orders of government should work together to ensure the effective implementation of these international obligations.

Recommendation 11: Building on the report of the Federal-Provincial-Territorial Working Group on Regulatory Reform, the federal government should work with provincial and territorial governments on two priorities:

- developing a common and consistent regulatory approach to environmental assessments. Given that environmental assessments often have an impact on Aboriginal communities, federal and provincial/territorial governments should also involve Aboriginal peoples, where they have key interests; and
- exploring a cooperative approach to regulating in the area of biotechnology and emergent technologies.

Federal Regulatory Coordination

Recommendation 12: The Privy Council Office should establish a mechanism to support interdepartmental discussion and foster the development of government-wide positions on regulatory issues and ensure that departments take appropriate action to align regulations with national priorities.

Recommendation 13: Overarching regulatory policy frameworks should be developed that spell out the government's objectives in a sector or area of regulation. These frameworks would provide overall guidance to the various regulatory authorities and ensure that regulatory action is coherent and integrated. For example, policy frameworks should be established for sectors such as biotechnology and issues such as international regulatory cooperation.

Recommendation 14: The federal government should provide stakeholders and the public with single window access. It should also take a leadership role in working with other orders of government to create single window service.

Recommendation 15: In the case of significant investment projects, the federal government should designate coordinators with the appropriate decision-making authority to oversee the regulatory involvement of various federal departments.

Risk Management

Recommendation 16: The federal government should develop a risk management framework for regulation that would include the three following core elements: risk prioritization, risk assessment, and risk communication and consultation.

Recommendation 17: The federal government should undertake periodic risk scanning exercises and ensure that regulatory programs and resources are allocated to address Canada's risk priorities.

Recommendation 18: The federal government should develop a federal risk assessment standard or guidelines for regulation that would include:
- a federal strategy to systematically and strategically access the best scientific information and knowledge to support regulatory decisions;
- the coordination of risk assessments across departments;
- the classification and prioritization of risks, including the identification and publication of the risk priorities of each regulatory department;
- regular scanning of the public policy environment;
- systematic re-evaluation of these risk priorities in order to account for advances in information and science, results accomplished by the regulatory programs and changes in the public environment, and to respond to new sources of risk; and
- a regular review of the government's scientific capacity.

Recommendation 19: Federal departments should frame and establish processes for the application of precaution in specific situations, such as when the potential risks or benefits to society are a high priority; when the level of scientific uncertainty is high; when there is a significant lack of societal consensus due to a fundamental clash of values; or when the regulatory framework is unclear or inadequate for addressing new emerging risks. For these situations, they should:
- develop protocols and processes for decision making and how they plan to use precaution in decision making;
- explain the rationale for the use of the precautionary principle to the public;
- consider independent peer reviews to assess the rationale for acting rather than waiting for more evidence; and
- commit to the regular review of significant decisions based on the precautionary principle to determine if information has become available that is relevant to the decision.

Recommendation 20: The federal government should develop and publish federal guidelines for risk communication that provide:
- a clear and transparent explanation of the rationale for decisions and how they were made, including the relative weight assigned to the various factors used in decision making; and
- a strengthened role for the federal government as a reliable provider of scientific and other relevant information to consumers, parliamentarians and the media.

Recommendation 21: The federal government should develop guidelines on how public engagement could be used to gain a better understanding of public risk tolerance and to obtain input into key risk management issues and options.

Instruments for Government Action

Recommendation 22: The government should develop a framework for the design and use of a mix of instruments, including compliance and enforcement strategies. It should also establish mechanisms to ensure that instrument decisions are more strongly debated throughout the policy development cycle, notably by requiring that the Privy Council Office's challenge function be exercised earlier in the process.

Recommendation 23: The federal government should accelerate efforts to make the regulatory community aware of the various instruments available and the benefits of using a combination of tools to solve policy issues.

Recommendation 24: Legislative constraints on creating mixes of policy instruments and using performance-based regulations should be eliminated.

Recommendation 25: The government should examine expanding the appropriate use of economic instruments in Canada. Efforts could include the following:
- examining the opportunities and challenges associated with EFR in Canada and addressing whether and, if so, how EFR could be implemented to support environmental policy goals;
- identifying several economic instruments which could be used to attain environmental policy goals and assessing their effectiveness, either individually or as part of an instrument mix;
- identifying areas where fiscal measures act as disincentives to achieving environmental policy objectives and finding ways to redress the situation; and
- launching pilot initiatives to examine the effectiveness of economic instruments in achieving policy objectives. For example, the government could design and implement one or more pollutant charges or taxes as well as incentives to accelerate the adoption of innovative environmental technologies.

The Regulatory Process

Recommendation 26: The Government of Canada should give priority to developing a new federal Regulatory Policy that would:
- reflect the Committee's vision, principles and proposed regulatory strategy as outlined in this report;
- apply to broader aspects of regulatory intervention, including statutes, regulations, specified quasi-legislation and the negotiation of international positions; and
- target or "tier" the procedural requirements to accommodate such matters as level of risk and impacts.

Recommendation 27: Existing statutes should be reviewed to identify and remove impediments to Smart Regulation. Statutes and regulations should be clearly drafted and allow for the use of modern regulatory techniques.

Recommendation 28: The government should implement a risk-based approach to regulatory action to improve analysis and decision making by requiring that all proposals for regulatory statutes and "significant" or "very significant" regulations be accompanied by an appropriately tiered risk-based policy analysis. The risk-based policy analysis should be open for public comment and reviewed by experts in the relevant discipline.

Recommendation 29: The government should strengthen the performance measurement of regulation by requiring that all proposals for regulatory bills and "significant" and "very significant" regulations be accompanied by a public performance measurement plan.

Recommendation 30: The government should ensure that attention is paid to regulatory program implementation and compliance early in the policy development process by requiring that "significant" and "very significant" regulations be accompanied by a compliance plan.

Recommendation 31: The Department of Justice, the Privy Council Office and federal departments should work in collaboration to introduce legislation that would make a range of compliance measures available to all departments.

Recommendation 32: The government should improve its capacity to approach consultation as a dialogue that promotes collective learning about risks, options for instruments, effective compliance strategies and the potential impacts of regulatory action. It can do this by improving coordination, increasing financial support to consumer groups, exploring new consultation techniques or mechanisms, and developing and disseminating guiding principles to more clearly frame consultation exercises.

Recommendation 33: The government should capitalize on the potential of e-government as a tool for citizen engagement and as a vehicle for single window access to government regulatory programs; in particular, a Smart Regulation gateway and departmental virtual regulatory agenda should be established and maintained.

Recommendation 34: The government should develop new approaches to allow for more timely development and approval of regulations, including exploring broader exemptions from pre-publication requirements, improving project planning discipline and developing performance standards for appropriate stages of the regulatory process.

Recommendation 35: The government should improve efficiency, timeliness and predictability, and enhance transparency in the provision of government services. This should include the development of service standards and the use of e-government as a vehicle for single window access to government regulatory programs.

Recommendation 36: The government should establish an ongoing program of evaluation and modernization of existing regulation to ensure that regulation evolves with social needs and scientific advances. A mechanism by which the public can suggest areas of regulation for priority review should be established.

Recommendation 37: The government should establish performance criteria and measures for the regulatory process to ensure the principles and objectives of Smart Regulation are being fostered.

Recommendation 38: The federal government should establish a recourse mechanism independent of the regulatory program to provide an opportunity to stakeholders and citizens to challenge regulatory performance and decisions.

Recommendation 39: Another external advisory committee should be convened in the medium term (e.g. two years) to assess the government's progress in transforming the regulatory system.

Government Capacity

Recommendation 40: The government must develop and implement a comprehensive learning strategy for the regulatory community.

Recommendation 41: The government should develop and implement regulatory policy research and development agendas in collaboration with appropriate partners from outside the public service.

PART II: SECTORS/AREAS OF REGULATION

Manufacturing and Product Approval

Recommendation 42: The federal government should work with stakeholders and citizens to develop an inventory of regulatory differences, particularly between Canada and the U.S., that impede Canadian competitiveness. They should be examined using the criteria for Canada-specific requirements. If regulations do not meet these criteria, Canada should take immediate action to align its regulatory requirements.

Recommendation 43: A comprehensive Canadian automotive policy framework is required in order to coordinate automotive regulatory roles and develop clear objectives. This framework would also incorporate a strategy of cooperation on standards and joint regulatory development with the U.S.

Recommendation 44: The federal government should further develop its international cooperation framework for the regulation of therapeutics to include short- and long-term objectives and timeframes, and it should proceed quickly with the implementation of this framework to achieve a level of performance reflecting international best practices.

Recommendation 45: The federal government's short-term efforts should be focused on implementing measures to use data and reviews produced in other jurisdictions when an independent Canadian process does not add to the quality of outcomes. Longer-term efforts should focus on establishing mechanisms to maximize the benefits for Canadians of the knowledge and regulatory capacity developed in other jurisdictions in order to provide timelier access to new therapeutic products.

Recommendation 46: Health Canada and the Department of Justice should explore and recommend, in the context of the renewal of the *Food and Drugs Act* and other health protection statutes, what immunity might be appropriate to the department and its staff. The recommended approach should be consistent with the protection provided to other leading therapeutic product regulators, including the U.S. Food and Drug Administration and Australia's Therapeutic Goods Administration.

Biotechnology/Life Sciences

Recommendation 47: The government should make it a priority to develop and implement a comprehensive, government-wide biotechnology regulatory strategy which would:

- identify and address legislative gaps, implement systematic international cooperation, and provide accessible and comprehensive information about regulatory developments;
- identify ways to access and draw from the expertise of the domestic and international scientific communities;
- give due consideration to ethical issues;
- provide opportunities for input from all stakeholders and for citizen engagement;
- be translated into a detailed work plan that measures and reports on progress;
- be reviewed regularly and modified to account for progress in implementation and the rapid changes that characterize biotechnology; and
- assign clear and effective accountability for its strategic leadership and management.

Recommendation 48: The federal government should identify, prioritize and address legislative gaps impacting biotechnology. As a first step, it should accelerate the renewal of health protection legislation. To ensure legislation also continues to be appropriate, it should be monitored via regularly scheduled reviews that are provided for in legislation or in departmental mandates. When appropriate, independent scientific advice and public input should be sought in these reviews.

Recommendation 49: The federal government should be actively and strategically involved in international regulatory cooperation activities impacting biotechnology. It should encourage international and domestic experts to participate in independent peer reviews of studies, risk assessments and regulatory analysis. It should also identify instances where it is in Canada's interest to be a regulatory leader and actively pursue this objective.

Recommendation 50: The federal government should implement an enhanced communications strategy which would include an accessible Web-based consumer and industry information service similar to the U.K.'s Biotechnology Regulatory Atlas and effectively inform target audiences of its existence and benefits.

Recommendation 51: The federal government should devise and implement a thorough and sophisticated approach to engage citizens and other stakeholders on public policy issues involving biotechnology. This should include the sharing of information on current scientific evidence and risk management analysis.

Enabling First Nations Economic Development

Recommendation 52: The federal government must move quickly to create an efficient, more responsive regulatory environment in First Nations communities, thereby enabling them to realize full economic growth. A key element in designing a successful approach should be to improve cooperative arrangements between First Nations, governments and industry.

Recommendation 53: Working with First Nations, the federal government should accelerate its agenda to introduce new legislation or amend existing legislation as necessary, so that bands have the benefit of a modern regulatory regime in the shortest possible time. In addition, the federal government should move immediately to address regulatory gaps that inhibit the development of commercial and industrial projects on reserve.

Recommendation 54: The federal government should review the full scope of regulatory activity in First Nations communities with a view to reducing the regulatory and administrative burden placed on them. Outdated or duplicative regulations should be eliminated and regulatory gaps addressed. In support of this initiative, the government should put in place a centralized process or mechanism to ensure better coordination and monitoring of regulatory activity in communities.

Recommendation 55: The federal government should accelerate the development of initiatives to improve the skills and capacity of First Nations to make rules and manage regulations. As a key step, the government should give priority to developing the appropriate legislation that would help strengthen the professional skills base in First Nations communities.

The Environmental Assessment Process

Recommendation 56: The federal government should begin discussions with the provincial and territorial governments to develop a nationally integrated environmental assessment process for Canada in which the different jurisdictions would collaborate as partners.

Recommendation 57: The federal government should create a single environmental assessment agency in order to carry out assessments under federal jurisdiction and collaborate with other orders of government.

Recommendation 58: Multiple environmental assessments on the same project conducted by different authorities should be conducted concurrently, not sequentially.

Recommendation 59: The Canadian Environmental Assessment Agency and potential substitute authorities, such as the National Energy Board, should negotiate an agreement to enable substitution when an environmental assessment by a review panel and other project approval processes are both required.

Recommendation 60: Specific targets, performance measures and indicators for monitoring a project's environmental impacts and the effectiveness of mitigation measures should be considered essential elements of environmental assessments. This approach would incorporate lessons learned from past assessments, post-approval audits and reports on monitoring. These elements need to be developed in consultation with the provinces, territories and other regulators, particularly if a national environmental assessment process is eventually established.

Recommendation 61: The government should conduct public strategic environmental assessments to provide people with an opportunity to discuss overall development issues in the offshore regions or on federal lands, or issues related to a potential new federal policy or policy change.

Recommendation 62: Fisheries and Oceans Canada should accelerate its implementation of planned improvements to its fish habitat system and related involvement in environmental assessment.

Recommendation 63: The *Comprehensive Study List Regulations* should be evaluated to ensure that the greater complexity of the process (compared with screening) would result in improved environmental protection. Consideration should also be given to modifying the list of projects or altering thresholds where experience has demonstrated that a comprehensive study is warranted because there is a potential for significant adverse environmental effects.

Recommendation 64: Participant funding must be recognized as an essential element of environmental assessment to enable citizens to participate in the assessment process. Guidelines for participant funding should provide clear criteria as to who should receive participant funding in the environmental assessment process and for what purposes.

Recommendation 65: The federal government, in consultation with Aboriginal communities, should provide guidance on how Aboriginal traditional knowledge can be factored into an environmental assessment, while ensuring the balance necessary to maintain viable project timeframes.

Oil and Gas Exploration and Development

Recommendation 66: The government should continue to play a leadership role in building on the shared vision embodied by the Cooperation Plan to create a broader, long-term regulatory cooperation framework among northern regulators that offers timeliness, transparency, predictability, clarity and certainty.

Recommendation 67: The federal government should implement a single window approach to coordinate the involvement of federal regulators in the regulation of industry sectors in the North (e.g. oil and gas, mining), incorporating mandatory timelines for regulatory responses to project submissions to ensure timeliness and certainty.

Recommendation 68: To encourage the efficient regulation of the Mackenzie Gas Pipeline, it is proposed that a federal coordinator be appointed as soon as possible with clear decision-making authority vis-à-vis the various departments and accountability to implement a coherent regulatory environment for the MGP.

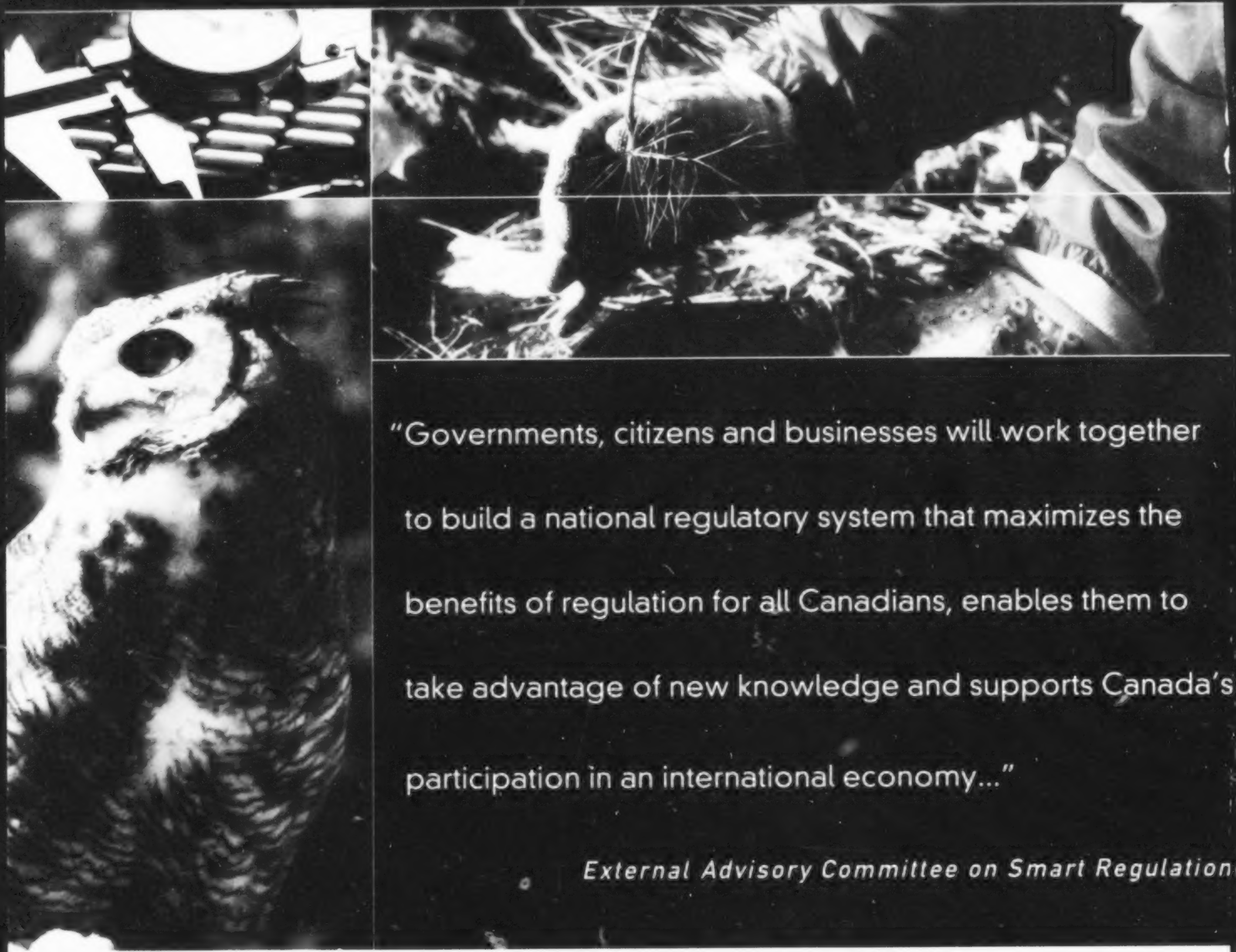
Recommendation 69: The federal government should provide training for all new northern regulatory board members as a condition of appointment and as ongoing support. The federal government should also work with similar boards and tribunals across northern Canada to create a network to share best practices and solutions to the challenges facing them.

Recommendation 70: As Fisheries and Oceans Canada proceeds to develop regulations under the *Oceans Act*, it should ensure that these measures are established in consultation and collaboration with other federal and provincial regulatory authorities, industry, First Nations and other stakeholders. This approach should complement existing regulations governing offshore oil and gas seismic activities.

Recommendation 71: Federal government interaction with the offshore oil and gas industry and other stakeholders should be guided by an overarching regulatory policy framework linking all relevant federal departmental responsibilities.

Recommendation 72: Performance-based regulation should be developed in areas that would enable safety and environmental approaches to be adapted to specific risks as they are encountered, and new technology to be incorporated quickly, while meeting economic, social or environmental regulatory performance expectations.

Recommendation 73: The government should ensure that the multistakeholder Regulatory Advisory Committee studying the policy, which requires comprehensive study assessments of exploratory wells, completes its deliberations and takes appropriate action in a timely manner.



> "Governments, citizens and businesses will work together to build a national regulatory system that maximizes the benefits of regulation for all Canadians, enables them to take advantage of new knowledge and supports Canada's participation in an international economy..."

External Advisory Committee on Smart Regulation